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June 1986

FSIS Future Agenda

Response to the NAS Recommendations

**United States
Department of
Agriculture**



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RESPONSE TO THE NATIONAL ACADEMY OF SCIENCES REPORT
FOOD SAFETY AND INSPECTION SERVICE
AGENDA FOR THE FUTURE

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PREFACE

In order to maintain consumer confidence in the Nation's meat and poultry supply during a period in which many changes have taken place in meat and poultry inspection, the Food Safety and Inspection Service (FSIS), in November 1983, contracted with the National Academy of Sciences (NAS) to review, from a scientific point of view, the ability of the inspection program to maintain the traditional level of consumer protection. The NAS report, published in July 1985, found that the inspection program, even with its changes, was maintaining consumer protection. It made recommendations for ensuring that the program would be able to maintain that standard and, perhaps, even improve its performance, in a world that is becoming more technologically complex.

The NAS report postulated an "optimum" model of meat and poultry inspection and compared the current FSIS program with that model. It found that the current FSIS program measured up well to that model. This, of course, is no surprise, because FSIS started its program modernization about eight years ago and has made considerable progress during that time in accommodating new detection and production technologies. Where the current program deviated from the optimum model, NAS made recommendations for improvements.

As part of its long-range planning process, FSIS has, over the past year, reviewed each NAS recommendation, evaluated its relevance to the Agency's responsibilities and capabilities, and presented a range of options for effecting desirable changes. The scope of the review is reflected in the following document. Experts from within and without the Agency endeavored to provide every possible course of action available to FSIS in implementing an approach to inspection that would meet or exceed the elements of the NAS optimum program. In each case a preferred course of action was identified and recommended with the understanding that the final decisions would rest with senior officials in USDA. Those decisions have now been made and are contained in Chapter I, Subpart E of this report. As a result, the Agency has added to its agenda a set of activities designed to increase both the efficiency and effectiveness of its inspection program over the next five to ten years.

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FOOD SAFETY AND INSPECTION SERVICE
AGENDA FOR THE FUTURE

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CHAPTER I

FOOD SAFETY AND INSPECTION SERVICE AGENDA FOR THE FUTURE

RESPONSE TO THE NATIONAL ACADEMY OF SCIENCES REPORT
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A. INTRODUCTION

In the late 1970's, the Food Safety and Inspection Service (FSIS), then the Food Safety and Quality Service, initiated a long-range program to modernize meat and poultry inspection. Its objectives were twofold: to ensure that inspection methods would be adequate to protect the public against new hazards to the food supply, particularly those related to chemical contamination; and, in the face of pressures to reduce Government expenditures, to increase the productivity of inspection to enable current resources to cover the ever-growing job of protecting the meat and poultry supply.

These two goals were not in conflict. Advances in science and technology had made it possible to develop production and inspection processes that were both more effective and more efficient. The Agency set out to improve its ability to deal with chemical hazards by building a new laboratory system in order to improve its analytical methodologies. It set out to improve the efficiency of inspection by streamlining tasks when healthier animals and new production technologies increased industry's ability to consistently produce a product in compliance with the law. These activities were the beginning of the move away from the continuous, labor-intensive, organoleptic inspection methods of traditional inspection established in the early 1900's toward a risk-based, analytical system built upon modern scientific and industrial technologies.

In 1986, FSIS published its Strategic Plan that lays out the Agency's goals for the modernization of meat and poultry inspection through FY 1992. The Agency's Strategic Plan is founded on six organizational objectives which express the overall philosophy and guiding principles of the FSIS meat and poultry inspection program. The six FSIS organizational objectives are:

- o PUBLIC PROTECTION
- o RISK-BASED ALLOCATION OF RESOURCES
- o USE OF ADVANCED SCIENCE AND TECHNOLOGY
- o SHARED RESPONSIBILITY WITH INDUSTRY
- o ENHANCED ENFORCEMENT
- o MORE EFFICIENT HUMAN RESOURCE UTILIZATION

The FSIS Strategic Plan is included under Section B below.

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B. FSIS STRATEGIC PLAN FY 1988-92

The FSIS Strategic Plan for the period from FY 1988 through FY 1992 is made up of two parts. The first part, entitled FSIS Organizational Objectives, reaffirms several principles that continue to guide our tradition of fostering a food supply that is safe and wholesome and one that has earned the confidence and trust of the American people. Nothing that we do to improve inspection will in any way sacrifice these principles.

The second part of the plan contains the Strategic Policy Goals. Each of the Goals is intended to promote the Organizational Objectives by spelling out the specific Agency policy that will govern our decision-making and planning activities for the next five annual budget cycles. The Goals do not provide specifics. They provide general direction, organizational philosophy, and policy. However, the specific way in which each program achieves the goals and objectives articulated in this plan will remain the prerogative of Agency managers.

FSIS ORGANIZATIONAL OBJECTIVES

- o PUBLIC PROTECTION -- Protection of the public from public health hazards and economic adulteration is the primary objective of meat and poultry inspection.
- o RISK-BASED ALLOCATION OF RESOURCES -- The allocation of inspection resources should be based on the risks to the public inherent in a product, a process, or a producer.
- o USE OF ADVANCED SCIENCE AND TECHNOLOGY -- The inspection program will take full advantage of the available production and scientific technologies to increase productivity and improve the effectiveness of inspection.
- o SHARED RESPONSIBILITY WITH INDUSTRY -- The meat and poultry industry should be encouraged through education, incentives, and enforcement to share with the Government the responsibility for public protection.
- o ENHANCED ENFORCEMENT -- The Agency will seek stronger penalties for violations of the Federal meat and poultry inspection laws.
- o MORE EFFICIENT HUMAN RESOURCE UTILIZATION -- The Agency will increase and expand the variety of technical and program development skills available to the inspection program.

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STRATEGIC POLICY GOALS

The policy guidance contained in this portion of the Strategic Plan provides to Agency managers the instructions to be used when preparing detailed plans for their individual program areas. The response that the Agency makes to important external developments such as the NAS Committee report recommendations and changing budget priorities and legislative initiatives will be directed by the policies articulated in the Strategic Plan and reflected in the FSIS Multi-Year Plan and Annual Program Plan for the corresponding fiscal year.

1. MODEL OF INSPECTION

In carrying out its activities to improve the effectiveness of public protection and to increase the efficiency of inspection methods, FSIS will design its overall system of enforcement to ensure public confidence in the meat and poultry supply.

POLICY INTENT

It is FSIS' intention to structure its current programs and to make any major modifications to them in such a way as to ensure that public confidence remains high in the meat and poultry supply. Public protection will not be sacrificed or in any way compromised by modernization efforts and efficiency-enhancing changes to inspection. New technologies and new approaches to inspection will be assessed to ensure that they at least maintain current levels of public protection.

2. SCOPE OF AUTHORITY

FSIS will seek additional authority where appropriate to meet the Agency's public protection objectives.

POLICY INTENT

To date, the Agency has sought amendments to increase its authority to determine the degree of inspection intensity in processing plants and to refuse to provide or withdraw inspection service. As opportunities to improve the effectiveness and increase the productivity of inspection activities are identified, further changes may be required in existing authority. The policy of FSIS for the five years of the planning period is to pursue such changes in its authority.

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3. INFORMATION RESOURCES MANAGEMENT

FSIS will explore the need for and expand the utilization of IRM systems necessary to carry out its mission more effectively and efficiently.

POLICY INTENT

The Agency's policy for the next five years is to identify and allocate the resources to information systems required to implement the Agency's management and enforcement system activities as effectively and efficiently as possible.

4. SCIENCE/TECHNOLOGY

FSIS will increase the application of science and technology through research and development to enhance the effectiveness as well as the productivity of inspection.

POLICY INTENT

The Agency has moved from an organoleptic approach in ante and post mortem inspection to one that employs the latest developments in chemistry, microbiology, food technology, and electronic information systems. Nevertheless, the pace at which FSIS applies and develops scientific and technological knowledge must be quickened. The Agency's policy for the planning period is to increase its effectiveness in dealing with such problems as chemical and microbial contamination and disease monitoring. Among other things, this means that the Agency must find more ways to control its own research and development agenda.

5. EMPLOYEE TRAINING/DEVELOPMENT

FSIS will recruit and train employees to achieve and maintain skill levels required to carry out its mission by restricting the Agency's training resources to training that cannot be, or is not likely to be, obtained elsewhere at private (non-Agency) expense.

POLICY INTENT

In the past, the new techniques and skills necessary to support inspection modernization have been, for the most part, taught at Agency expense to new employees. The cost of this training has represented a sizeable portion of the overall Agency budget. In order to upgrade the skills of its employees within available resource constraints, the Agency will in the planning period pursue a policy of recruiting and hiring persons who are already trained in specialized skills such as food science, food technology, pathology, and public health. Training funds will

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be used to support training in applied meat and poultry inspection technologies and for positions that cannot be filled by outside recruitment.

6. EMPLOYEE AND LABOR/MANAGEMENT RELATIONS

FSIS will actively seek to broaden employee-supervisor consultation and communication opportunities, continue training in labor/management for supervisors and managers, and pursue a policy of sensitivity to employee concerns. It will also continue to maintain positive working relations with employee organizations and third party representatives by maintaining a strong, credible, and professionally-staffed labor management program.

POLICY INTENT

The Agency is committed to finding better ways to promote harmonious relations between employees and managers. This may be done through a combination of labor/management sensitivity training, improved communications, and increased awareness by management of the problems faced by the labor force.

7. EQUAL EMPLOYMENT OPPORTUNITY/CIVIL RIGHTS

FSIS will provide employment opportunities and services in a non-discriminatory manner and strive to improve the representation of minorities, women, and handicapped individuals through progressive recruitment, outreach activities, and removal of employment barriers.

POLICY INTENT

The Agency's intention during the planning period is to identify and actively seek to remove or change any institutional barriers to the employment of women and minorities in the inspection program. As always, the policy of the Agency is to consider for employment any person who is qualified to perform the job for which he or she is being considered and to provide a work environment that is free from discrimination and harassment. The Agency will continue to utilize positive initiatives such as upward mobility and cooperative education programs as well as provide EEO training for supervisors to support the objectives of the EEO program.

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8. EXPORTS

FSIS will support industry efforts to expand trade by working closely with U.S. industry and Government agencies to identify and monitor regulatory impediments to potential markets and negotiate with foreign countries to reduce or remove such obstacles to overseas business.

POLICY INTENT

While recognizing that the Agency has a limited mandate in the international trade arena, FSIS will support the Administration's efforts in seeking means to expand trade by working closely with industry and cooperating with the appropriate Federal and State agencies and foreign governments.

9. INTERNAL COMMUNICATIONS

FSIS will improve systems to facilitate communications between and among all levels of the organization in order to promote participation, encourage responsive management, and strengthen uniformity in applying inspection regulations.

POLICY INTENT

FSIS has established many new communications procedures such as town hall meetings, newsletters, satellite teleconferences and supervisory conferences. It is the continuing policy of the Agency to seek to improve existing communications channels, promote a more widespread and general awareness of their existence, and identify other ways of providing even better access to program-related information. These improvements reflect the Agency's commitment to providing a work environment which enables employees to perform to their fullest potential. This includes developing an organizational structure that best suits the needs of the Agency's large and geographically dispersed workforce.

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C. NATIONAL ACADEMY OF SCIENCES STUDY

Critics of the Agency's modernization program have viewed the reduced dependence on inspector presence as a threat to the standard of protection. In order to help the public understand that new technologies were available that could provide more and better information for inspection purposes than could be obtained by an inspector's continuous presence, FSIS asked the National Academy of Sciences (NAS) to evaluate the effects of its innovations on the standard of protection. The NAS report, Meat and Poultry Inspection--the Scientific Basis of the Nation's Program, published in July 1985, presented in some detail an agenda for the continuation of the Agency's plan to modernize inspection.

The NAS Committee described the characteristics of what they saw as an optimum meat and poultry inspection program. Most of these characteristics were already present in the FSIS program, and many of them represented the type of innovations that the Agency had undertaken, or was proposing to undertake. Where, in its opinion, the Agency deviated from this optimum program, the NAS Committee recommended the initiation of new activities or the expansion of present activities to more fully cover existing risks. This report is FSIS' response to those recommendations.

FSIS and the NAS Committee agree that the way to modernize meat and poultry inspection is to use advances in science and technology to move inspection from a labor-intensive, organoleptic process that attempts to sort wholesome from unwholesome animals or birds at the slaughtering plant to a system that (1) focuses on the elimination and control of diseases and other unwholesome conditions early in the animal production chain; (2) monitors systems of production rather than individual animals to minimize public health risks in the production process; and (3) gives full responsibility to industry for complying with the meat and poultry laws.

In responding to the NAS recommendations, FSIS has tried to be realistic about what is desirable, what is possible, what is necessary, and what good management can produce. To a large degree, FSIS hopes to support many of the new and expanded activities recommended in response to the NAS report by improving the efficiency of inspection and releasing resources to be allocated to these activities. However, before significant increases in efficiency can be obtained, a certain base of complementary activities must be in place to improve the productivity of inspection resources. Some of those activities such as quality control inspection processes in both slaughter

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and processing plants are in place. In order to be in a stronger position to generate inspection efficiencies, FSIS needs to make a sizable investment in the development of new inspection technologies and in automated data information management. However, it is not clear that the Agency has enough discretionary funds to make this necessary investment.

As the NAS report recognizes, FSIS has shown a willingness to make changes and to act on the basis of scientific and technical evidence that its program needs improvement. The NAS report concludes that FSIS must now do a better job of developing tools and methods that can be used in inspection, and that to do this, the Agency "needs to obtain the kind of research backup for its program that would both enhance its scientific and public credibility and provide the technical base required for sophisticated policy analysis."

FSIS has a clear understanding of its goals and has established strategies for achieving those goals. This response to the NAS recommendations is part of FSIS' multi-year planning activity and is based on the Agency's vision of the future--what a good inspection program should look like in 20-30 years, and what it will take to get there. The NAS report has given credibility to this vision and to the Agency's plans for achieving an "optimum program."

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D. FSIS REVIEW PROCESS

After the NAS report was published, FSIS organized a series of committees to respond to the report's recommendations. These committees and their assignments corresponded to the major recommendations in the report. The eight committees were as follows:

- o Animal ID and Traceback
- o Microbiological Contamination
- o Residue Control
- o Disease Control
- o Data Systems
- o Methods Development Agenda
- o Agency Technical Capability
- o Public Education

Each committee had members from both inside and outside FSIS because so many of the regulatory problems discussed by the NAS report were beyond the jurisdiction of FSIS. (A detailed list of committee memberships is contained in an attachment at the end of each report).

Each Committee evaluated a wide range of options in making the recommendations that appear here. The NAS report and this activity associated with it provided the Agency with the opportunity to step back and look at its program through the eyes of others. This activity fortunately coincided with the Agency's new long-range planning activity. Thus, after decisions are made with respect to the general activities suggested in this report, the Agency is prepared, through its planning mechanism, to elaborate on the implementation requirements for these activities and establish responsibilities and schedules for their effectuation.

The following reports present a complete analysis of the NAS recommendations and FSIS objectives and strategies related to the various problem areas, as well as the detailed reasons why specific options were selected or discarded.

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E. SUMMARY OF MAJOR NAS RECOMMENDATIONS AND THE FSIS RESPONSE

1. METHODS DEVELOPMENT AGENDA

NAS RECOMMENDATION

To achieve the goal of installing a modern technology-based system of inspection, the NAS recommended that "FSIS develop a capability for conducting or contracting for scientific and technical research tailored to its needs, rather than depending on other USDA agencies."

FSIS RESPONSE

FSIS will request from Congress funds to support a methods development activity. The Agency will continue to use the Agricultural Research Service for that research ARS is willing to do and is able to do in a timely fashion.

2. RESIDUE CONTROL

NAS RECOMMENDATION

NAS recommends that residues be controlled at their point of entry into the food chain, i.e., that prevention of residues is the most effective way to control them.

FSIS RESPONSE

FSIS is planning to conduct the following activities to control residues at their point of entry into the food chain: (1) continue to encourage and support industry involvement in avoiding residue problems throughout the animal production process; (2) initiate an animal identification program for swine; (3) increase incentives, such as the use of voluntary certification, to prevent residues; (4) use interagency cooperation to effect closer coordination between detection and prevention; and (5) continue to support the development of rapid screening tests.

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NAS RECOMMENDATION

The NAS recommends there should be clear acceptable quantitative limits for all important substances.

FSIS RESPONSE

FSIS supports the amendment of the Federal Food, Drug, and Cosmetic Act, and Poultry Products Inspection Act to facilitate the establishment of tolerances as recommended by the Sub-cabinet Council Working Group on Food Safety chaired by USDA. FSIS will also review animal drug responsibilities distributed across several agencies to facilitate coordination between detection and enforcement activities.

NAS RECOMMENDATION

The NAS recommends an increase in the sample size of FSIS' residue monitoring activity to improve its ability to prevent consumer exposure.

FSIS RESPONSE

The residue monitoring sample is designed to provide information on incidence, not to prevent exposure. It is unrealistically expensive to change the focus of monitoring to prevention of exposure. The Agency agrees it needs, and intends, to improve the management of information generated in the monitoring activity to enable it to focus the integrated set of residue control activities on prevention.

NAS RECOMMENDATION

The NAS recommends that formal risk assessment play a prominent role in residue control activities.

FSIS RESPONSE

FSIS will continue to rely primarily on FDA and EPA for hazard assessment of chemical residues in livestock and poultry products. At the same time, the Agency is planning to enhance its Compound Evaluation System prototype (which ranks compounds based on risk expressed as a function of hazard and exposure) and its capability to generate and use quantitative exposure data. FSIS will continue to participate in interagency risk assessment endeavors and to evaluate its needs for achieving an independent capability for conducting formal risk assessment.

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NAS RECOMMENDATION

The NAS concludes that the analytical tools and testing capacity of FSIS are inadequate and that the Agency should continue to make revisions to accommodate changing needs. In particular, it noted the continued need for rapid, inexpensive screening tests to detect a broad array of hazardous chemical compounds.

FSIS RESPONSE

FSIS agrees that it must have the capacity to undertake methods development research and intends to ask Congress for support to build the capacity to develop more rugged, easily performed rapid screening tests for laboratory, in-plant, and on-farm use. The Agency also intends to explore ways of increasing its laboratory capacity.

NAS RECOMMENDATION

The NAS recommends that FSIS improve the link between testing for residue contamination and regulatory enforcement.

FSIS RESPONSE

FSIS intends to improve the coordination of policymaking and residue-related program activities in the field by developing explicit guidelines for implementing all facets of the residue control program and centralizing responsibility for execution and review of residue functions.

NAS RECOMMENDATION

The NAS recommends that FSIS decisionmaking be more open to participation by outside experts and interested members of the public.

FSIS RESPONSE

FSIS believes that a variety of mechanisms may be useful to increase openness and to encourage input from outside the Agency. It intends to explore (1) the institution of regular reviews of monitoring and exploratory testing priorities; (2) the desirability of holding an annual meeting to discuss the operation of Federal residue programs; (3) disseminating the Agency's testing priorities more widely; (4) the feasibility of issuing expanded reports on the results of residue testing, and (5) mechanisms to increase the public's understanding of chemical residue control.

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3. MICROBIOLOGICAL CONTROL

NAS RECOMMENDATION

The NAS recommends that FSIS increase its current efforts to control and eliminate contamination with microorganisms which cause foodborne illness in humans.

FSIS RESPONSE

FSIS believes that it must find ways to reduce or eliminate microbiological contamination in fresh meat and poultry products at the time of slaughter or further processing. FSIS intends to evaluate and use slaughter, dressing, and processing procedures which have the potential to contribute to microbiological control and to develop a set of complementary activities such as in-plant sanitation procedures, information and education activities, and a definitive disease diagnosis program that will support a major microbiological control initiative.

4. DISEASE CONTROL

NAS RECOMMENDATION

The NAS recommends that FSIS undertake a definitive diagnosis activity that will help the Agency focus on the prevention of diseases throughout the animal production chain.

FSIS RESPONSE

FSIS does not have the laboratory capacity to institute a full-scale activity of this kind, so it will initiate a small definitive diagnosis activity with the objective of developing and testing associated in-plant and laboratory procedures and other regulatory mechanisms that could be used in an expanded activity in the future.

5. ANIMAL IDENTIFICATION

NAS RECOMMENDATION

The NAS recommends that an animal identification system be established so that diseased or contaminated animals can be traced to their source, the farmers' share of responsibility for contamination can be clearly established, and epidemiological studies of specific disease outbreaks can be facilitated.

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FSIS RESPONSE

FSIS will begin to implement this recommendation by promulgating a regulation that requires slaughter plants to maintain records on the ownership of all swine for a 30-day period immediately preceding slaughter. The Agency is planning to evaluate this system, and if appropriate, expand it to other animals.

6. DATA SYSTEMS

NAS RECOMMENDATION

The NAS recommends a heightened use of data in FSIS programs. The NAS also recommends that the overall data analysis capability of the Agency be upgraded.

FSIS RESPONSE

FSIS will need additional resources to build a modern data management system and will request funds from Congress for this purpose. Assuming the availability of funds, the Agency intends to: (1) improve the design of its data bases; (2) improve the Agency's capability in the interpretation of data for management decisionmaking; (3) improve the quality of information and its accessibility to FSIS managers, and (4) improve the collection and timeliness of data.

7. AGENCY TECHNICAL CAPABILITY

NAS RECOMMENDATION

The NAS recommends that FSIS increase its access to technical expertise by the use of advisory committees, continuing education and training for its staff, and more interagency liaison with relevant scientific and animal health agencies.

FSIS RESPONSE

As outlined by its Executive Team in the Agency's Strategic Plan, FSIS is planning to improve its accessibility to technical expertise by using as a guideline the realities of the marketplace (i.e., who can the Agency successfully recruit and keep) and the cost of training. After analyzing its needs for more expertise and the constraints presented by the marketplace and the cost of training, FSIS has decided to recruit food

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technologists who are already trained in their disciplines (food science, food technology, pathology, public health, etc.) and to use its training resources to educate Agency personnel in applied meat and poultry inspection technologies. For specialists that the Agency only uses from time to time, or which it is at a comparative disadvantage in recruiting, FSIS will utilize advisory or contractual modes. The Agency intends to use a Basic Ordering Agreement, a form of contract that allows the flexible use of scientific personnel and other expertise, to obtain services as needed. FSIS will also investigate the appropriateness and desirability of using more advisory groups.

8. PUBLIC EDUCATION

NAS RECOMMENDATION

The NAS recommends that the Agency continue public education activities to ensure that meat and poultry are handled properly after they leave the Agency's jurisdiction.

FSIS RESPONSE

FSIS plans to continue its present public education program with more targeting of messages for specific audiences -- health care personnel, educators, institutional food preparers, and others -- to improve the overall effectiveness of the education program. The Agency also plans to work with various industry segments to encourage expanded food handling information on its product packaging.

10. RISK ASSESSMENT

NAS RECOMMENDATION

The NAS recommends that risk assessment be systematically employed in the planning and evaluation of all phases of meat and poultry inspection.

FSIS RESPONSE

FSIS has already initiated risk-based allocations of resources in slaughter and processing plant procedures and has requested authority from Congress to pursue additional risk-based reallocations in the processing sector. A new NAS study is

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exploring the possibility for developing a sampling model to replace bird-by-bird inspection for broilers. It must have the potential to increase the efficiency and effectiveness of poultry slaughter procedures, but also provide a risk assessment model for the Agency to effect additional innovations. FSIS will continue to enhance its system of risk assessment for residue control and import inspection.

CHAPTER II

METHODS DEVELOPMENT AGENDA RECOMMENDATIONS

METHODS DEVELOPMENT AGENDA RECOMMENDATIONS

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METHODS DEVELOPMENT AGENDA RECOMMENDATIONS

A. STATEMENT OF PROBLEM

In accord with the Administration's desire to improve the productivity of the government sector, FSIS plans to increase the use of modern technology in its inspection program. To implement this strategy, the Agency must make a significant investment in the development of new technologies to carry out inspection. FSIS has been unable to fully take advantage of scientific advances to develop new inspection technologies because it does not have adequate funding for the methods development that this strategy requires. Further, certain mechanisms for accessing least-cost R&D performers are not available to FSIS.

The Agricultural Research Service (ARS) performs research for FSIS, but ARS does not meet all of the methods development needs of FSIS. This comes about for several reasons. First, research dollars are in great demand and the competition is keen for these limited resources. Second, many of FSIS' developmental needs are linked to ongoing ARS programs. This allows ARS to schedule FSIS research within its existing budget and management plans. However, this can result in FSIS' needs not being represented in the central core of research being undertaken by ARS.

A formal ARS/FSIS mechanism currently exists to coordinate the research of ARS scientists to fulfill the needs of FSIS. Despite the shortcomings mentioned herein, this approach has worked extremely well in upgrading ARS' response to FSIS' developmental needs over the last five years. Much valuable information has surfaced as a result of this approach; however, a plateau has been reached and other means of satisfying FSIS' methods development needs must be explored if the full range of the Academy's recommendations are to be realized.

METHODS DEVELOPMENT AGENDA RECOMMENDATIONS

B. NAS RECOMMENDATION

To achieve the goal of installing a modern, technology-based system, the committee recommends that "FSIS develop a capability for conducting or contracting for scientific and technical research tailored to its needs, rather than depending on other USDA agencies." They did not, however, differentiate between the research conducted by ARS and the methods development carried out by FSIS.

METHODS DEVELOPMENT AGENDA RECOMMENDATIONS

C. FSIS OBJECTIVES AND STRATEGIES IN THE PROBLEM AREA

FSIS agrees with NAS that it does not have the resources to conduct the methodology development activities that it needs to put its inspection program into the technology-based mode that the NAS says is necessary to maximize consumer protection. An important part of the Agency's plans to modernize inspection is to use advances in science and technology to increase the effectiveness and efficiency of its inspection resources. One of the Agency's strategic planning goals is to increase its effectiveness by focusing on-line inspection away from animal-by-animal sorting and onto activities to prevent diseases and conditions that present public health hazards. In order to implement this strategy, the Agency must make a significant investment in the development of new technologies. To date, the Agency has been unable to adequately carry out these activities. The reasons for the Agency's inability to conduct adequate developmental activities include:

1. INADEQUATE FUNDING

There are inadequate funds available within FSIS to support these activities. Seven years ago the Agency requested funds from Congress to support laboratory services. Although funds were authorized, with the exception of \$5 million spread over the 7 years, Congress refused to appropriate any new funds for these activities during this period. The Agency has had to use what was left of these funds after basic laboratory services had been funded to help solve critical inspection problems such as those related to the use of sorbates, nitrite levels in bacon, bone particles in mechanically deboned products and protein quality. No money has been available for "non-emergency" developmental projects. As a result, the Agency has found itself unprepared to address effectively some immediate inspection problems such as the dosimetry needed to enforce irradiation compliance; serological tests for detecting some diseases or conditions in animals which present serious public health hazards; rapid, flexible, inexpensive methods for detecting hazardous chemicals; etc.

2. NO OTHER SOURCE FOR METHODS DEVELOPMENT ACTIVITIES

Within the Department of Agriculture, only ARS has the authority to conduct basic research. Thus, as mentioned, in recent years FSIS has looked to ARS to meet its research and development needs. ARS has been able to help FSIS meet the unique needs for methodological development to the extent feasible, but both agencies recognize the limitations that exist. However, ARS is frequently not in

METHODS DEVELOPMENT AGENDA RECOMMENDATIONS

a position to modify or create new methods development efforts to adequately supplement the FSIS activities in the development of methodology tailored for inspection and regulatory needs.

3. ACCESS TO CONTRACTORS

FSIS does not have R&D procurement authority. Thus, the Agency cannot conduct the flexible pre-award negotiations with prospective performers that are essential in selecting the best contractor in R&D projects, e.g., the ability to conduct orals with two or three technically qualified contractors regardless of cost proposals. In complicated developmental activities, proposals may not be an adequate basis on which to differentiate performers, particularly when new ideas, not prescribed in the Request for Proposal, are presented in the proposals.

Further, Cooperative Research Agreements, necessary to reach land-grant college R&D performers, many of whom have experience in the developmental areas which FSIS needs, are available to FSIS only through ARS.

The above problems have (1) limited the scientific and technical developmental activities of FSIS, (2) complicated the process of initiating work, and (3) created unnecessary inefficiencies in projects that have been undertaken. To correct these problems, FSIS needs to be able to use a variety of sources for its scientific and technical developmental work, thereby taking advantage of suppliers' experience and incentives to both maximize the usefulness of this work and keep the costs of this work as low as possible. For example, where projects involve the building of models of inspection, it is frequently most efficient to do this within FSIS itself. It not only assures that the researchers have an intimate understanding of the whole array of program needs and constraints and can, therefore, most efficiently adjust technical possibilities to the environment, but also it avoids expensive education of scientists or technical people not well-versed in all aspects of the inspection program.

When FSIS needs scientific and technical information on the safety or effectiveness of food substances, it should be looking for experience in those areas. Since the Food and Drug Administration must continuously make decisions about the safety and effectiveness of food substances for its own regulatory purposes, FSIS can usually get these kinds of evaluations done most efficiently by FDA.

METHODS DEVELOPMENT AGENDA RECOMMENDATIONS

When FSIS needs a rapid test to detect a disease or other condition in animals or carcasses, it should be looking to organizations that have developed similar tests. The profit-oriented organization can frequently be motivated to undertake expensive developmental projects at relatively low cost to the government on the expectation that it will have a product that FSIS will buy to use in the inspection process. FSIS should be taking advantage of its potential as a significant customer to get developmental work done by the private sector.

METHODS DEVELOPMENT AGENDA RECOMMENDATIONS

D. OPTIONS EVALUATION AND FSIS RECOMMENDATIONS

OPTIONS

1. Option: Ask Congress for an FSIS appropriation to support analytical methods development and similar research activities necessary to modernize the inspection program and solve unique short-term food safety problems. As an alternative, or in addition to a request for new funds, the Agency could seek a reprogramming of a certain portion of USDA research monies to be placed under FSIS management authority.

Assessment: Past experience does not indicate that this option has a high probability of success. However, in view of the strong Academy recommendation in this area, it may be time for appropriate Assistant Secretaries and budget officials in USDA to critically review this matter.

2. Option: ARS and FSIS will increase their efforts to foster closer working relationships between the scientists of the two agencies in order to more nearly meet the scientific and technical needs of FSIS.

Assessment: Under this option, the two agencies would continue the existing mechanism for coordination with a stronger management commitment to foster closer working relationships between the scientists of the two agencies. Efforts would focus on fostering an understanding of the priorities, timeframes, and job expectations that the scientific and technical staffs of both agencies work under.

3. Option: Ask the Office of General Counsel for a formal interpretation with respect to whether FSIS is authorized to use Cooperative Research Agreements without going the competitive route, and if it is OGC's opinion that we are not, ask Congress for that authority.

Assessment: FSIS recognizes that ARS will continue to facilitate cooperative agreements with appropriate institutions to help FSIS better meet their needs related to methodology development. However, there are times when it is simply unnecessary and, therefore, inefficient to have ARS involved. There are other times where it would be more appropriate to have the agreement between FSIS and a participating university, i.e., when the scientific staff working most directly on the problem resides in FSIS and not in ARS.

METHODS DEVELOPMENT AGENDA RECOMMENDATIONS

4. Option: Supplement ARS research by accessing the Special Currency Program (P.L. 480) funds to do methodological development by: (1) discussing potential projects with scientists in foreign countries where funds are available, (2) providing the Office of International Cooperation and Development with a list of our developmental interests so they can try to obtain potential performers, and (3) developing a methods development protocol to meet FSIS needs.

Assessment: This option would clearly identify an additional source of funding for FSIS developmental activities.

5. Option: Include in FSIS procurement regulations the provisions, used by many other agencies to procure R&D services, that allow more flexible pre-decision contacts with prospective contractors.

Assessment: This option would facilitate contracting at the lowest cost with the assurance that technical products will meet Agency's standard.

FSIS RECOMMENDATION

The Agency recommends that it pursue Option 2 and the remaining options be pursued by the Office of the Assistant Secretary for Marketing and Inspection Services.

ATTACHMENT A
MEMBERSHIP OF METHODS DEVELOPMENT COMMITTEE

COMMITTEE CHAIR

Lou Gast, Associate Administrator
Food Safety and Inspection Service

SECRETARIAT

Judith A. Segal, Director
Policy and Planning Staff
Food Safety and Inspection Service

Mary Carter, Associate Administrator
Agricultural Research Service

Al Post, Special Assistant to
the Deputy Administrator
Science
Food Safety and Inspection Service

John Prucha, Assistant Deputy
Administrator
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

CHAPTER III

RESIDUE CONTROL RECOMMENDATIONS

RESIDUE CONTROL RECOMMENDATIONS

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RESIDUE CONTROL RECOMMENDATIONS

A. BACKGROUND

The NAS Report's evaluation of the "Management of Chemical Hazards in Meat and Poultry" (Chapter 4) focused on residues of chemicals that are present either as a result of their use in the production or distribution of food or as a result of accidental or environmental contamination. Thus, pesticide chemical residues may result from the treatment of feed crops or persistent contamination of the soil as well as from use in animal production. For example, animals may be treated with drugs directly or through their feed, or exposed when good manufacturing practices are not followed. Animals may also be exposed, directly or indirectly, to other substances not intended for use in food production or distribution.

To manage the potential risks to the food supply posed by chemical substances, Congress has established a system, under which a number of agencies play important roles. In particular, the Food and Drug Administration's (FDA's) responsibility for regulating foods for humans and other animals excludes livestock and poultry products to the extent that these foods are regulated by the United States Department of Agriculture (USDA) pursuant to the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) administered by the Agency (FSIS). In addition, FDA's responsibility for regulating the use of chemicals in food production and distribution excludes pesticide chemicals, which are regulated by the Environmental Protection Agency (EPA). These tolerances and action levels are enforced by the FDA. EPA's responsibility for regulating industrial chemicals (i.e., chemicals not regulated as pesticides, food or color additives, or animal drugs) also affects the management of potential risks to the food supply.

With the increasing application of chemical responses to agricultural problems after World War II and the development of methods for detecting residues of these and other substances at progressively lower levels came concern about potential risks. One Federal Government response was USDA's initiation of the National Residue Program (NRP). The program was intended to monitor the occurrence of various residues nationwide in different categories of animals and to assist in the protection of the public against adulterated foods through surveillance (i.e., targeted investigation and control activities). As part of the NRP, FSIS now also conducts exploratory residue testing and participates in residue avoidance efforts to prevent and correct problems through improved management practices.

RESIDUE CONTROL RECOMMENDATIONS

B. NAS COMMITTEE REPORT

The NAS committee addressed chemical hazards in meat and poultry by identifying "optimal characteristics that should be incorporated" in a program to assess and manage this area "if the NRP were being designed today" (p. 55) and then comparing this "optimal program" with the current NRP:

As a result of the committee's preliminary comparison of this optimal program and the current NRP, it believes that the NRP's primary objective -- the protection of the public health -- is correct but that the program falls short in implementing that objective in a number of important ways. [NAS report, pp. 56-57]. [see Table, page III-3].

The NAS committee found that the Agency has made some progress (e.g., in the development of better analytical methods and the allocation of greater resources) and that the NRP meets the primary objective of such a program. However, it also found that "the current program is seriously deficient in 3 of the 10 major characteristics of an optimal system" (sampling scheme adequacy for prevention, formal risk assessment, and an open process for priority setting) and that "although progress has been made in the other 6 categories, improvements are still needed." (p. 58).

FSIS has evaluated the conclusions of the NAS committee with respect to accomplishing the overall goal of public protection through the federal regulatory system and specifying the role that FSIS should play in attaining this objective. The remainder of this paper addresses the primary objective and each of the specific characteristics recommended for an "optimal system."

RESIDUE CONTROL RECOMMENDATIONS

Table 4-3 A Chemical Residue Program: Comparison of Characteristics and Current NRP

Optimal Characteristics ^a	Current NRP	Comment
Public protection as the major objective.	Public protection is the major objective.	Meets the objective.
Focus on prevention.	Focus is primarily on detection; some change since 1981.	Some progress made; still needs improvement.
Clear tolerance levels available on all important substances.	All important substances do not have tolerance levels.	Progress made; still needs improvement.
A sampling scheme adequate for prevention.	Sampling scheme is not adequate for prevention.	Deficient.
Formal risk assessment.	Risk assessment is not currently done.	Deficient.
Adequate analytical tools and testing capacity.	Testing capacity has improved but is still inadequate.	Some improvements made.
A trained inspection service.	Current training is insufficient in some areas.	Needs improvement.
Close links to regulatory enforcement.	Structure of FSIS tends to discourage communication.	The field operations and NRP need closer ties.
Useful information system.	Systems are adequate for current needs but not for anticipated problems.	Still needs improvement.
Priorities set through an open process.	Priorities are set by a closed process.	Deficient.

^aFor details of optimal characteristics, see pages 54-58.

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C. RESPONSE TO NAS COMMITTEE CONCLUSIONS AND RECOMMENDATIONS

1. Public Protection

The NAS committee's basic conclusion was that:

[T]o ensure the public health safety of meat and poultry requires that procedures used must continually identify chemical hazards, measure consumer exposures, evaluate the health responses to those exposures, and provide risk characterizations. The results of these assessments must be the subject of constant open and objective discussions and critiques. The overall goal should be a regulatory system that manages public health risks associated with chemicals in meat and poultry by integrating the results of scientifically developed risk assessments with consideration of the political, social, and economic realities. [p. 59].

The Agency agrees that this is the appropriate overall goal for the federal regulatory system as a whole. FSIS' NRP is an integral part of that system, which also includes FDA, EPA, and other USDA agency programs.

In comparing an optimal chemical residue program with the current NRP, the NAS committee concluded that the current NRP meets the criterion of:

Public protection as the major objective. [p. 57].

The Agency agrees that public protection is and should be the major objective, not only of the NRP, but of the entire inspection program. This commitment is clearly stated in the Agency's Strategic Plan. However, FSIS believes that the following, more specific statement of that objective, with respect to the NRP, is appropriate:

Protection of the public against livestock and poultry products adulterated with chemical residues is the major objective of the NRP.

FSIS feels that this statement more accurately reflects the orientation of the current NRP. To promote this objective, the Agency has established several long-range policy goals which, when implemented, will utilize advanced science and technology applied on the basis of risk to ensure that the public is protected from harmful chemical residues.

RESIDUE CONTROL RECOMMENDATIONS

2. Focus on Prevention

The NAS committee identified a focus on prevention as an optimal characteristic and concluded that the focus of the NRP is primarily on detection; although there has been some change since 1981, improvement still is needed (p. 57):

The primary focus of the program should be prevention. Detection of problems can have little deterrent effect alone, especially in the absence of trace-back and with the very low sampling fractions. An emphasis on prevention implies major efforts to detect as well as to characterize hazards with respect to environmental or other sources, including suppliers, types and locations of affected food-animals, levels of contamination, correlation among contaminants, and other features. The link between testing for hazards and preventing them should be strengthened. Each finding of a violation should be reviewed to determine preventive measures. [p. 55].

The "committee concluded that the most effective way to prevent or minimize hazards presented by certain infectious agents and chemical residues in meat and poultry is to control these agents at their point of entry into the food chain, i.e., during the production phase on the farm and in feedlots [where] FSIS has no jurisdiction" (p. 6). It "noted that voluntary identification (trace-back) programs have had some success in the swine and poultry industries due to [their] changing structure (...vertical integration)" and "[r]ecent evidence also suggests that cooperative programs between farmers, slaughterers, and the Government can be effective in minimizing problems before they reach the slaughterhouse" (p. 7). The NAS committee recommended that to prevent consumer exposure, the NRP should:

Control the entry of chemicals at the farm. Introduction of an animal identification and trace-back system...will be very useful. [p. 60].

a. Agree or Disagree

FSIS agrees that residue control programs should focus on prevention, and agrees also that detection is an essential component of a prevention orientation. The Agency believes that the production of meat and poultry is a process involving such phases as the raising, feeding, and medicating of animals; the hauling, auctioning, and sale of animals; and ultimately, the slaughter of animals. The entire process

RESIDUE CONTROL RECOMMENDATIONS

must be controlled, with prevention measures built in at each phase. End product testing alone cannot prevent chemical residues. The Agency believes that a variety of options should be explored with industry and other interested members of the public to improve the manner in which FSIS, in cooperation with other agencies, seeks to prevent potentially harmful chemical residues in livestock and poultry products.

b. Options

(1) Encourage and support increased industry members' involvement in avoiding residue problems throughout the entire animal production process, from farm to slaughter by:

(a) Continuing and improving the current industry-conducted, FSIS-verified production control system, and seeking to expand the use of such a system, particularly within the red meat industry.

(b) Continuing the Residue Avoidance Program (RAP) to educate producers and others in improved management systems that avoid illegal residues:

- o Develop a formal agreement between FSIS, Extension Service (ES), and the Extension Committee on Organization and Policy (ECOP) as to conduct of the RAP effort.
- o Further develop and evaluate the Food Animal Residue Avoidance Databank (FARAD) as a RAP information resource, including its use in identifying problem areas for increased surveillance.
- o Identify and implement necessary studies, demonstration projects, and methods development to ensure the availability of state-of-the-art knowledge of management, economics, and market factors that prevent or mitigate residue problems.

(c) Developing standards of husbandry practice (by FDA in consultation with USDA) for food animal producers which encompass medication recordkeeping and animal identification as key points. These standards would be disseminated through RAP and also would be an integral part of industry-conducted, FSIS-verified production control.

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(2) Increase incentives to prevent adulterating residues by:

(a) Encouraging the development of market incentives, e.g., voluntary certification programs.

(b) Imposing direct economic penalties on producers and others (e.g., feedmill operators and dealers) whose actions are responsible for violative residue levels. New legislation would be required.

(3) Improve interagency coordination and cooperation in order to strengthen the link between testing (detection) and prevention by:

(a) Increasing interaction between FSIS, ES, Agricultural Marketing Service (AMS), Packers and Stockyards Administration (P&SA), FDA, and EPA at both headquarters and field levels so that roles are well defined and lines of communication are firmly established (see sections C.2.b and H.2 of this report).

(b) Cooperatively reviewing violations and other information to develop preventive measures for each phase of the meat and poultry production process.

(4) Continue to seek and fund development of additional rapid screening tests (such as CAST, STOP, and SOS) for use on the farm, in feedlots, and at slaughter (see also Chapter 6).

Several relevant aspects of residue control are treated elsewhere in this report and will not be covered here: characterization of hazards from a risk assessment and risk management perspective (see Subpart 5, Formal Risk Assessment, below) and sampling (see Subpart 4, Sampling Scheme, below). Also, animal identification and trace-back are being addressed in another area of this document (see Chapter VI). The inability to identify the producer(s) of animals with adulterating residues limits the effectiveness of investigative efforts to determine the cause and extent of contamination problems. FSIS, therefore, supports the development of feasible, cost-effective means of animal identification that would facilitate trace-back and enhance residue prevention activities.

c. FSIS Recommendation

The Agency feels all the above measures would help focus residue control on prevention. A strong prevention-oriented federal system must combine regulation with education and

must enlist the cooperation and support of federal and state agencies and all segments of the meat and poultry and other relevant industries. FSIS recommends, therefore, that all of these options be pursued, while recognizing that two of them -- a(2) and d -- will require significant additional resources.

3. Quantitative Residue Limits

The NAS committee identified the availability of clear tolerance levels -- i.e., precisely stated quantitative limits -- for all "important substances" or chemicals to be regulated as an optimal characteristic of a chemical residue program. While the NAS committee found that progress has been made in this area, it noted that improvement still is needed; there are not such levels for all "important substances." (pp. 55, 57.)

The NAS committee's evaluation also includes recommendations regarding the establishment of tolerances. Recognizing that the legislative mandates of FDA, EPA, and FSIS divide tolerance-setting and other authorities, the NAS committee recommended that "mechanisms be created to bring the standard-setting and enforcement arms of the Government closer together." (p. 60). As regards this broader area, the NAS committee concluded that:

The selection of chemicals for control and the tolerance level (or perhaps levels) for each should be based on a single, consistent set of principles for protecting the public....The establishment of tolerances should include evaluation of their adequacy as a public health protective measure, the adequacy of the data base supporting tolerances, and the adequacy of dealing with multiple residues, metabolites of residues, and multiple exposures from sources other than meat and poultry. [p. 55.]

a. Agree or Disagree

The Agency agrees that the development of additional, precisely stated limits on the quantities of various chemical substances in livestock and poultry products should be a goal of the federal regulatory system. However, FSIS does not agree with the apparent assumption that such limits are necessary before a substance can properly be considered for investigation or control (see p. 55). As regards substances not intended for use in food production or distribution, investigative surveys and other exploratory efforts help

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provide the basis for assessing the need for and appropriateness of specifying a particular quantitative limit; control of specific contamination incidents on a case-by-case basis also may be appropriate to protect the public health. As regards substances intended for such uses, the fact that the question of an acceptable residue level has not been addressed indicates that investigative and control activities may be needed to protect the public. The more immediate problem in each of these areas may be methodological: when a substance has not been evaluated for uses expected to result in residues in a livestock or poultry species, the likelihood that adequate analytical tools are available to determine its presence in that species is decreased.

FSIS also agrees in principle with the recommendation that the standard-setting and enforcement arms of the Federal Government should be brought closer together. A well-integrated federal regulatory system is essential if the public protection goal is to be achieved. Inadequate coordination in the implementation of various statutory mandates has diminished overall effectiveness. Among other things, this has in the past resulted in residue limits that are neither defined with sufficient precision nor associated with methods adequate for enforcement and in a lack of agreed-upon priorities. Finally, FSIS agrees that the factors noted by the NAS committee (see p. 55) should be considered in the development (and reevaluation) of residue limits. The Agency believes that current law provides for the inclusion of these factors as part of a basically consistent set of regulatory principles, although some statutory refinements and clarification may well be appropriate to improve tolerance-setting and enforcement functions.

b. Options

(1) Amend the Federal Food, Drug, and Cosmetic Act (FFDCA) and USDA's inspection laws (Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA) to facilitate the development and application of appropriate residue limits. As part of its review of federal food safety laws, the Sub-Cabinet Council Working Group on Food Safety evaluated the criteria and procedures now utilized in regulating the presence of various chemical substances in foods and, in early 1983, made recommendations for changes in light of scientific developments and federal regulatory experience. Congressional enactment of the Working Group's recommendations would, among other things, set the stage for increased availability of clear residue

RESIDUE CONTROL RECOMMENDATIONS

limits and coordination of EPA, FDA, and USDA functions and responsibilities. For example, recommended amendments in the pesticide chemical area would facilitate EPA establishment of tolerances, including interim tolerances (both on a short term basis for unanticipated residues and a more long term basis for residues of persistent, cancelled pesticides). Other recommended amendments would clarify and better define the limit-setting and enforcement roles of FDA and USDA in the areas of animal drugs and contaminants. In light of the NAS committee's report and other recent developments (e.g., the D.C. court of appeals' 1985 opinion in Community Nutrition Institute v. Young regarding FDA's responsibilities in the area of unavoidable contaminants, now being reviewed by the Supreme Court), it also may be appropriate to reconsider the precise scope of some of the Working Group's recommendations.

(2) Institute measures to assure increased interagency coordination. Despite the acknowledged reality that Congress has established a federal regulatory system which requires close coordination among FDA, EPA, and USDA programs and some improvements over time, there has not been adequate consultation and communication on an ongoing basis. The agencies currently have sufficient authority and resources to pursue activities that could result in meaningful improvements. In fact, the stage for such action was set at the beginning of 1985 by the adoption of a Memorandum of Understanding (MOU) regarding residue regulatory activities which replaces older, separate (i.e., two-agency) agreements and provides a structure for regularizing interaction and assuring accountability: senior level responsibility for implementation, an oversight committee with periodic reassessment responsibilities, and a task force approach for marshalling appropriate human resources to address particular needs. The structure has not yet been fully activated. FSIS believes that effective implementation of the MOU would address certain concerns of the NAS committee (e.g., bringing limit-setting and enforcement closer together) and increase the overall effectiveness and efficiency of the federal regulatory system. In addition to the vehicles specifically mentioned in the MOU, the Agency notes that computerized data systems and teleconferencing networks would improve communications at both headquarters and field levels. Limited efforts in this area have already been initiated between FSIS and FDA.

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Finally, the Agency notes that interagency coordination has been inhibited by confidentiality clauses in several federal statutes. FSIS recommends that these statutory provisions be reevaluated to facilitate interagency exchange of toxicological and other data relevant to federal control of potential chemical residue hazards.

(3) Amend the FFDCA and the FMIA and PPIA, realigning responsibilities to bring the standard-setting and enforcement arms of the federal government closer together. Different allocations of responsibilities among federal agencies have been considered and, on occasion, adopted. Recent adjustments have centralized most animal drug-related regulation in a single FDA component (Center for Veterinary Medicine (CVM) -- except for the enforcement activities of USDA -- and centralized pesticide (and other toxic chemical) regulation in EPA -- with FDA and USDA residue limit enforcement. In view of the breadth of EPA's role (e.g., toxic chemicals in addition to pesticides, multiple and potentially cumulative avenues of exposure to pesticide chemical residues through the total food supply and other, environmental sources), jurisdictional changes do not appear to be a viable option as regards pesticide regulation. Such changes might be considered a more viable option as regards animal drug regulation: FDA's CVM is primarily concerned with the use of substances that may result in residues in edible products regulated by FSIS. Thus, particularly if the previous two options are viewed as not offering sufficient potential for improvements, it can be argued that consolidating CVM's and USDA's responsibilities in USDA would improve effectiveness and efficiency through better management of priorities.

c. FSIS Recommendation

The Agency recommends implementation of the 1985 MOU to assure increased interagency coordination, and it believes that enactment of certain recommendations of the Sub-Cabinet Council Working Group on Food Safety would set the stage for increased availability of clear residue limits. FSIS also notes the possibility of exploring various consolidation options concerning animal drug related responsibilities from CVM to USDA.

4. Sampling Scheme

As regards sampling for chemical residues, the NAS committee identified adequacy for prevention as the criterion for an optimal program and found the NRP deficient in this regard (p. 57). "The committee's overall impression is that the sampling system is primarily determined by laboratory capacity rather than by judgments about the size and nature of an optimal program to protect the public health" (p. 58). The NAS committee recommended that "the NRP consider strategies to prevent consumer exposure to potentially hazardous chemicals"; it should, among other things:

Revise the residue sampling plan (e.g., increase the sample size and confidence level) to minimize consumer exposure. To ensure that optimal procedures are devised, appropriate recent advances in science and technology must be drawn upon. [p. 60.]

a. Agree or Disagree

In evaluating the residue testing aspect of the NRP, the NAS committee focused solely on the monitoring sampling scheme. FSIS does not agree that adequacy for prevention is the appropriate criterion by which to evaluate the monitoring sampling scheme, although it would be appropriate to recommend that all FSIS residue testing components contribute to a protection-oriented program which focuses on prevention. Also, the Agency agrees with the NAS committee that current inadequacies in documentation of and information on NRP operations, and the judgments underlying those operations, inhibit evaluation of the adequacy of current efforts (p. 53).

The Agency disagrees with the NAS committee's recommendation that the basic sampling scheme used in monitoring be revised "to minimize exposure" by, "e.g., increas[ing] the sample size and confidence level" (p. 60). The monitoring component of FSIS residue testing is and should be designed primarily to provide profile information on the occurrence of detectable levels of residues in different categories of animals on a nationwide, yearly basis. The extent to which exposure to various chemical substances should be minimized in order to protect the public health is considered during the development of residue limits for one or more categories of animals by FDA or EPA. Where such an evaluation has not taken place (i.e., there is no residue limit for any species), FSIS utilizes available information in determining the need for exploratory residue testing (e.g., to develop additional information on the frequency and levels at which a particular substance of potential concern is occurring). The information from monitoring and exploratory testing should be

RESIDUE CONTROL RECOMMENDATIONS

useful in identifying potential problems in production or distribution that can be addressed by other residue control efforts, such as surveillance testing and investigation of production practices for residue avoidance efforts. This information also should be useful in assessing the adequacy of initial evaluations of potential human exposure.

It would be particularly inappropriate to revise the statistical design of the monitoring sampling plan to increase the probability level from 95 percent and lower the rate of occurrence from 1 percent on an across-the-board basis. If, for example, FSIS changed these criteria to 99 percent and 0.1 percent, respectively, the necessary sample size would increase 15-fold, at a cost of about \$540,000 per chemical analysis for each animal category (see attached tables). Such an expenditure on basic monitoring would not be justified (or feasible). The number of samples taken still would constitute only a minuscule fraction of the population of interest and, hence, have little deterrent effect. Moreover, this would be a detection approach and, thus, not consistent with changes geared to making the NRP a more effective part of a total federal effort that focuses on prevention.

FSIS believes that the information problems noted by the NAS committee must be addressed in order to have an appropriate basis on which to determine the extent to which modification of the current monitoring and exploratory sampling components is warranted to improve program effectiveness. For example, FSIS has already expanded monitoring by defining the population of interest as particular production classes (e.g., calves, young chickens) within animal species whose products compose a significant part of the human diet. FSIS also regularly expands the number of samples taken beyond the number needed to meet the 95 percent-1 percent criteria. (For example, the 1985 plan called for sampling 1,000 calves for antibiotics (not 300 as the NAS committee states [p. 54]), providing 95 percent probability of detecting residues occurring in at least 0.3 percent of the population of interest.) However, the objectives of these changes and their perceived contributions to program effectiveness have not been made explicit or subsequently evaluated for effectiveness. It also may be that other ways of supplementing the basic monitoring scheme, such as increased use of stratified sampling, would be useful. Moreover, decisions in this area have not been integrated into an overall federal regulatory effort, at least in any formal or regularized manner.

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SAMPLE SIZES AND COSTS* FOR SAMPLE SIZES REQUIRED TO DETECT A PROBLEM OF SPECIFIED PERCENTAGE-SIZE WITH SPECIFIED CONFIDENCE

Per- cent	90 Percent Confidence		95 Percent Confidence		99 Percent Confidence		99.9 Percent Confidence	
Viola- tive	Sample Size	Cost**	Sample Size	Cost**	Sample Size	Costs**	Sample Size	Costs**
35.00%	6	\$693	7	\$808	11	\$1,270	17	\$1,963
30.00%	7	\$808	9	\$1,039	13	\$1,501	20	\$2,310
25.00%	9	\$1,039	11	\$1,270	17	\$1,963	25	\$2,887
20.00%	11	\$1,270	14	\$1,617	21	\$2,425	31	\$3,580
15.00%	15	\$1,732	19	\$2,194	29	\$3,349	43	\$4,966
10.00%	22	\$2,541	29	\$3,349	44	\$5,082	66	\$7,622
5.00%	45	\$5,197	59	\$6,814	90	\$10,394	135	\$15,591
1.00%	230	\$26,563	299	\$34,532	459	\$53,010	688	\$79,457
0.50%	460	\$53,125	598	\$69,063	919	\$106,135	1379	\$159,261
0.10%	2302	\$265,858	2995	\$345,893	4603	\$531,600	6905	\$797,458
0.05%	4605	\$531,831	5990	\$691,785	9209	\$1,063,547	13813	\$1,595,263
0.01%	23025	\$2,659,157	29956	\$3,459,618	46050	\$5,318,315	69075	\$7,977,472

***AVERAGE COST PER RESIDUE ANALYSIS**

****VALUES ARE ROUNDED TO THE NEAREST DOLLAR**

RESIDUE CONTROL RECOMMENDATIONS

AVERAGE COST FOR RESIDUE ANALYSIS

Residue Test	No. of Samples	Total Cost/Sample	Total Cost	Avg Cost
Antibiotics	14458	\$82.07	\$1,186,568.06	
Arsenicals	2287	\$83.21	\$190,301.27	
Chlorhydrocarbons	10776	\$127.91	\$1,378,358.16	
Nitrosamines	1320	\$271.86	\$358,855.20	
Organophosphates	259	\$359.11	\$93,009.49	
Sulfonamides	9125	\$131.19	\$1,197,108.75	
Trace Elements	409	\$141.00	\$57,669.00	
Total	38634		\$4,461,869.93	
Average Cost for Residue Analysis:				\$115.49

Source: Thomas F. Riley, Total Direct Costs for Agency Sampling and Analysis Activities, U.S. Department of Agriculture, Food Safety and Inspection Service, Science Program, March, 1985, p. 6.

b. Options

(1) Improve documentation of and information on NRP sampling programs. FSIS currently has the most thoroughgoing residue sampling program in the Federal Government. However, as indicated by the NAS committee's evaluation, there is a lack of understanding of various aspects of these testing efforts attributable, at least in part, to inadequate documentation of decision making and recording and dissemination of information. Further improvements in this area can continue to be accomplished within the Science program and with current resources (assuming this is regarded as a high priority area.) Such improvements also appear to be a necessary prerequisite to decisions about the extent to which other changes are needed (see, e.g., other options), as well as fulfillment of FSIS's contribution to the total federal residue control effort.

(2) Develop explicit guidelines for determining when monitoring sampling should be expanded beyond the number of samples needed to meet the 95 percent probability-1 percent incidence criteria and for initiating and designing exploratory sampling subprograms. Because these judgments have tended to be implicit, they have not generally been subject to review by outside experts or interested members of the public for their internal consistency and utility in contributing to the public protection objective. Therefore, development of such guidelines would contribute to improved, goal-directed decision making. This option could be accomplished within FSIS with some redirection of current resources, and work could begin once efforts on the previous option have been initiated.

(3) Consider all available relevant data on residue occurrence. In evaluating the extent to which sampling efforts, including FSIS surveillance, should be modified, and in improving public protection through increased coordination of federal agency programs, consider all available relevant data on residue occurrence, particularly those from industry member sampling of carcasses and FDA sampling of dairy and egg products and animal feeds. A truly proactive or prevention-oriented approach to residue control requires a broad perspective in which data and other information collected pursuant to one program are not viewed parochially but rather are utilized, to the extent relevant, in other programs. Thus, for example, feeds are an important route of livestock and poultry exposure to pesticide chemicals.

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Similarly, information on drug residues in livestock and poultry products can be useful in evaluating and reevaluating the effectiveness of use conditions (e.g., labeling requirements) as part of a realistic regulatory system. It appears that improvements are possible if the previous two options and the interagency coordination efforts envisioned in the 1985 Memorandum of Understanding (MOU) regarding residue regulatory activities are pursued. FSIS has initiated activities in this area (e.g., in considering data already being provided by industry members and FDA). An increased effort in conjunction with the first two options and/or in conjunction with renewed interagency coordination under the revised MOU could require some additional resources.

c. FSIS Recommendation

FSIS recommends that documentation of and information on NRP programs be improved and that this work be utilized in decision making regarding other changes, including the development of explicit monitoring and exploratory sampling guidelines and the consideration of other relevant information.

5. Formal Risk Assessment

In evaluating the NRP against the optimal characteristic -- formal risk assessment -- the NAS committee stated "formal risk assessment does not appear to be conducted" and found the program to be deficient in this area. (pp. 57-58).

Formal risk assessment should play an explicit, prominent role in each of the [following] features...: setting of tolerance, focus on prevention and hazard characterization, priorities, and sample design. [p. 55].

The NAS Committee recommended that the NRP "[i]ntroduce formal risk assessment as a tool to provide maximum protection" (p. 61). "[T]he committee maintains that the NRP is not demonstrably adequate to ensure maximum protection of the public health" and "[a] more rational public health objective, based on concepts of risk assessment and risk management, would be to design the optimal system to ensure that no one person consistently receives a total exposure to levels of chemicals in excess of an established tolerance level." (pp. 59-60).

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a. Agree or Disagree

The Agency supports the use of a range of risk assessment approaches in developing residue limits for livestock and poultry products. FDA and EPA have used a variety of techniques including, for example, quantitative risk assessment approaches for carcinogens and safety factor approaches for other biological end points. The public has been apprised of the use of these techniques, which have been peer reviewed through Federal Register Notices. Moreover, Food, Drug, and Cosmetic Act requirements for substances permitted for use in the production or distribution of food provide that, in addition to safety considerations, a tolerance be set no higher than necessary for the purpose intended. There are ongoing systems for review of residue limits in EPA and FDA. In EPA this review, mandated by Congress, is a systematic process.

FSIS believes that continued use of a range of quantitative and other risk assessment techniques, depending on the type of chemical substance, hazard of concern, availability of data, and other pertinent factors, is appropriate for developing residue limits rather than imposing a unitary "formal" or "quantitative risk assessment" approach. The Agency also believes that appropriate risk assessment techniques should play an explicit and prominent role in program management decisions on sampling plans and in the allocation of resources for prevention-oriented activities, hazard characterization and methods development, and that the NRP would be strengthened by considering a number of options to improve its risk assessment and risk management capabilities. Finally, the Agency believes that a national public health goal toward which the NRP, as part of the federal regulatory system, should strive is to ensure that no one person receives a consistent exposure to residues in meat and poultry products above a level determined to be safe in setting the residue limits.

b. Options

(1) Continue to enhance the FSIS Compound Evaluation System (CES) by which residues are ranked according to their potential impact on public health for use in risk management decisions (e.g., in developing sampling plans, and allocating resources for methods development and residue prevention-oriented activities). The refined CES prototype under evaluation is designed to rank compounds based on risk, expressed as a function of two major elements: hazard and exposure. Peer review and comment from scientists within and outside of government as well as from the affected industries and other interested

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members of the public should be sought. As rapidly as resources permit, additional compounds should be evaluated, ranked and the basis documented. All relevant data in EPA and FDA files, to the extent not protected by confidentiality restrictions should be obtained. All possible means of compiling data, such as contracts, use of in-house personnel, and assistance from manufacturers, should be explored. The most cost-effective records system should be developed.

(2) Take steps to enhance FSIS capability for quantitative exposure assessment of chemical residues in livestock and poultry products by: (1) enhancing computer capability for the analysis of residue data, (2) adapting food intake data bases for compatible use with species/tissue-specific residue data, and (3) allocating resources for exposure assessment and publication of reports for use by managers within FSIS and other federal agencies concerned with chemical residues in food.

(3) Continue to rely primarily on FDA and EPA for hazard assessment of chemical residues in livestock and poultry products that result from use in food production or distribution, and improve interagency coordination in hazard evaluation and risk assessment for contamination of livestock and poultry products with other substances. Further consider the extent to which FSIS should have an independent capability for hazard assessment in meeting its responsibilities under the FMIA and PPIA.

(4) Continue participation in interagency risk assessment endeavors, and undertake a comprehensive evaluation of (1) the extent to which FSIS should establish an independent capability for formal quantitative risk assessment and (2) the means (including additional resources) needed to achieve the appropriate capability.

c. FSIS Recommendation

The Agency believes each of the above options is worthwhile and should be considered in conjunction with the recommendations on the Agency's technical capabilities.

6. Analytical Tools and Testing Capacity

The NAS committee concluded that while there have been some improvements in testing capacity, including the development of better methods for many chemicals, the NRP still is inadequate as to analytical tools and testing capacity (pp. 57,58). As noted earlier, the committee's overall impression was that laboratory capacity is the primary determinant of the sampling scheme (p. 58), and it felt that FSIS should continue to make revisions to

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accommodate changing needs since chemical testing is likely to increase relative to more traditional testing (p. 60). "Technical aspects of the testing program should be adequate to support the functions discussed above" (p. 55). In particular, the NAS committee noted the continuing need for "rapid, inexpensive screening tests to detect a broad array of hazardous chemical compounds..." (pp. 11, 152) and "more accurate,...sensitive,...less expensive tests as well as tests for new hazards", with quality control as a "prominent feature" (pp. 55-56).

There are substantial resource needs for an optimal program (p. 60), and the NAS committee recommended that "program staff and its advisors should have a strong voice in determining and meeting these research needs" (p. 56). Research needs include the development of economical tests for many chemicals, with sensitivity appropriate for relevant residue limits, that can be read while meat and poultry are still in the slaughterhouse and new tests for chemicals "continually added to the list of potentially significant hazards" (p. 60).

a. Agree or Disagree

FSIS is in basic agreement with the NAS committee's conclusion that improvements have been made in residue testing capability but more can and should be done to enhance FSIS's ability to protect public health. However, while the ability to change sampling rapidly in response to evidence of changing hazards is desirable, too great an emphasis on flexibility in monitoring and other sampling could lead to chaos within the field service laboratory system (e.g., analyst training and dedication of instruments to specific projects).

b. Options

(1) Provide adequate tools to conduct a residue monitoring program.

(a) Authorize FSIS to conduct a basic methods development program. To determine analytical methods needs, FSIS frequently requires information on questions such as the biochemical mode of action of a drug, its depletion characteristics in animals, and drug stability. This information is not always available from FDA, EPA, or manufacturers. Presently, FSIS does not have a basic research mandate and must rely upon ARS to generate the needed data for developing trace residue level analytical methods. FSIS's needs and priorities regularly conflicts with ARS's ability to respond. Authorization to conduct basic methods development would enable FSIS to develop an

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integrated methods development program on a more timely basis and allow ARS to pursue more long range needs.

(b) Improve utilization of external methods development:

(i) Fully implement all external funding mechanisms for conducting needed methods development. These should include grants and cooperative agreements which, according to USDA's Office of General Counsel's (OGC's) recent interpretation of the Federal Grant and Cooperative Agreement Act of 1977, are not presently available for methods development. OGC should be asked to review its interpretation of the 1977 Act, making full use of the U.S. Government Accounting Office (GAO) report supporting use of a range of funding mechanisms, and, if necessary, develop a potential legislative remedy.

(ii) Explore the relative effectiveness, cost, and efficiency of in-house vs. external methods development. Using extramural methods development would broaden and make more flexible the range of research skills and expertise at the disposal of FSIS and might enable more rapid responses to changing needs.

(c) Develop automated testing procedures. Technologies such as robotics may be used to automate methods and provide for unattended running of laboratory instruments or procedures increasing efficiency while cutting long-term-costs. Short term capital expenditures will be necessary to support this effort.

(d) Strengthen interagency cooperation in setting priorities for methods development. FSIS, in concert with FDA and EPA, should identify a priority list of chemicals/animal tissue combinations for which methods either do not exist or are not appropriate for routine regulatory use. This can be done with existing resources. A two-day meeting with FDA has been set for January 1986 to initiate this process for drug residues.

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(e) Increase coordination of the planning and monitoring function and methods development process. Formulation of a three to five year plan, updated annually, would provide for a more effective, rational, and timely methods development program that would lead to a smoothly operating and proactive system for methods development.

(2) Provide adequate analytical tools for increasing laboratory capacity.

(a) Explore the use of non-federal laboratories for residue testing. The present system may not be as cost effective as utilizing a contracting mechanism for residue analysis. For example, the average estimated cost for each residue sample analyzed in an FSIS laboratory has been estimated at a weighted average cost of approximately \$115. By comparison, the New York State Horse Racing and Wagering Board pays only \$10 per horse for seven blood-based drug screening tests performed at trackside. Only positives are forwarded to a central laboratory for additional analysis.

(b) Develop rugged, easily performed rapid screening tests for laboratory, in-plant, and on-farm use. Non-laboratory testing could extend the range of public protection and enable laboratories to focus resources on analyzing only potential positive residue samples.

(c) Establish an emergency response/special projects unit within the Science program. Such a unit with forensic capabilities would provide the laboratory facilities needed for rapid responses to emergency situations. It would help minimize the impact of such situations on the on-going NRP while providing the flexibility required to protect the public health. When such emergencies do not exist, this unit could be directed to methods development activities. Start-up costs for personnel, space, and equipment could be substantial but would provide a long-term benefit.

(d) Expand Quality Assurance/Quality Control (QA/QC) principles to complement existing FSIS laboratory programs. The importance of QA/QC must continue to be stressed for in-laboratory procedures and expanded to include non-laboratory screening procedures. The quality of in-plant and on-farm testing data could dramatically influence

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the credibility of residue programs. Guidelines for acceptable method performance and QA/QC procedures for screening tests do not exist but are currently being developed by the Association of Official Analytical Chemists for regulatory-related programs. FSIS personnel should continue to participate in that effort.

c. FSIS Recommendation

The Agency believes that each of these options would contribute to a more effective program for methods development and residue testing capability for public health protection. Certain options will require additional resources as well as coordination with other units in USDA and other federal agencies. Appropriate avenues for coordination will have to be explored as well as potential legislative remedies.

7. Trained Inspection Service

In comparing this optimal characteristic to the current NRP, the NAS committee found that current training is insufficient in some areas and improvement is needed (p. 57).

The inspection service, including those who select samples and those who collect them, must be trained for their roles. Industry, too, must train and educate their personnel to promote appropriate use of the testing program to protect public. [p. 56].

The efforts recommended by the NAS committee to meet changing needs include "recruitment and development of management personnel [a]nd the development of a capability for quantitative health risk assessment." (p. 60).

In an optimal meat and poultry inspection system, the NAS committee suggested that "managers should have expertise in several relevant disciplines, including veterinary medicine, food science and technology, nutrition, public health, and public management", but no one discipline should dominate management (p. 10). Furthermore, all phases of inspection should use "a technically qualified team with up-to-date knowledge of veterinary medicine, food science, public health, food engineering, food technology, epidemiology, pathology, toxicology, microbiology, animal science, risk analysis, systems analysis, statistics, computer science, and economics" (p. 10).

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(a) Agree or Disagree

FSIS agrees with the NAS committee's recommendations concerning the development and incorporation of a wide spectrum of technical and scientific capabilities in the inspection program at staff and management levels. In particular, personnel with sampling responsibilities (design and implementation) should be properly trained and educated for their respective roles, and the recruitment and development of management personnel should focus on anticipated needs. While recognizing the Agency's successful continuing education program and curriculum of inspection-related coursework, the Agency agrees with the NAS committee that further efforts are needed in particular areas to ensure that a qualified team is recruited and developed to meet the future challenges in meat and poultry inspection.

(b) Options

Because the Agency's technical capabilities are being reviewed and assessed elsewhere, specific options are not developed in this chapter on residue control. However, recommendations have been developed and should be considered under the technical capabilities chapter.

(c) FSIS Recommendation

The Agency recommends that means of providing training in quantitative risk assessment as well as other subjects that are relevant to residue sampling design and implementation should be sought. The Agency also recommends that resources be allocated to assure that an appropriate residue-related component is an integral portion of the mandatory technical training required for various inspection personnel. Lastly, FSIS recommends that both recruiting and training be utilized to assure a cadre of qualified personnel with expertise in relevant disciplines and management.

8. Close Links to Regulatory Enforcement

The NAS committee concluded that although prevention should be emphasized, the testing program as a whole should have close links to regulatory enforcement (because of the likelihood of chemical contamination inadvertently creating health hazards even with industry awareness and prevention), but the current structure of FSIS tends to discourage communication (pp. 56-57). "The field operations and NRP staff need closer ties" (p. 57). The NAS committee also noted that, while establishing an

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Agency-wide emergency response system may have improved communications, "[b]ecause of the organization of FSIS and the placement of the NRP within the Science component, it is difficult to know whether there is adequate communication at the operations level between the program staff and those in the enforcement part of the Agency" (p. 58).

a. Agree or Disagree

The Agency agrees that regulatory enforcement -- identifying adulterated products and taking action against responsible firms and individuals -- is an integral part of residue control. The Agency also agrees with the NAS committee's conclusion that for the NRP to be effective, communication between FSIS residue program and operations personnel must be improved. However, the Agency believes that the conclusion should be expanded to reflect the structure and operation of the federal regulatory system: Coordination must be a multi-agency effort. To function effectively, the system must assure that FSIS sampling results -- detection -- are coordinated with appropriate follow-up by EPA and FDA, sometimes with assistance from certain states, as well as FSIS. Linkage of these types of activities should be assured on both headquarters and field levels for consistency in policies and implementation procedures.

b. Options

(1) Expand the CRS concept to assure headquarters coordination of policymaking and field level implementation of residue-related programs; include appropriate Science and Operations Personnel in design and implementation. Interaction should consider inspection resource capabilities and priorities and field level perceptions of residue program needs. Explicit guidelines and instructions for implementing all facets of the NRP carried out by inspection personnel should be developed and updated periodically. Responsibility for execution and review of all FSIS field level residue functions should be centralized within Operations (and within International Programs as to imports). To achieve meaningful improvements in management and intra-agency coordination, additional resources (particularly personnel) are needed at the regional level.

(2) Increase coordination among FDA, EPA, and USDA headquarters and field levels; lines of communication must be firmly established and roles must be well defined and understood by those in other agencies. Responsibility for improving the interaction among agencies rests with all the agencies. As indicated above (see the option discussion in section C), adoption of the 1985 MOU on residue regulatory activities provides a structure for

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pursuing meaningful improvements with current resources and existing legislative authority. The Agency believes that such action is necessary to increase the effectiveness of the federal regulatory system and should include the computerized data systems and teleconferencing network possibilities noted elsewhere in this paper. In addition, FSIS's role as an MOU participant should include responsibility for coordination with P&SA and APHIS with regard to relevant regulatory activities (e.g., certification).

c. FSIS Recommendation

FSIS recommends that both of these options be pursued.

9. Information Systems

The NAS committee identified information system usefulness as an optimal characteristic of a chemical residue program and concluded NRP "[s]ystems are adequate for current needs but not for anticipated problems" (p. 57). The NAS committee recommended that the "NRP...promptly begin to develop an action-oriented information system for program management" in order to:

identify and track each violation for appropriate action; ...characterize hazards to assist in prevention and to guide in the development of sampling plans; and...monitor and improve quality control in the testing program [p. 60; see also p. 56, paragraph 4].

a. Agree or Disagree

The Agency agrees that further improvements in this area are necessary, but we believe that the problem is more extensive: Existing systems are not adequate for current needs, as indicated by other comments and recommendations of the NAS committee and its conclusion that "lack of information substantially inhibits program evaluation and tends to cast doubt on the NRP's utility, even if the program operations are in fact adequate" (p. 53) (see also, section D, Sampling Scheme, above).

The Agency also agrees that information system development should be oriented towards the objectives noted by the NAS committee. In fact, FSIS already has begun work in this area through its Information Resources Management (IRM) project in which the Science program and outside experts have been involved for the past year.

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As the NAS committee noted, the NRP currently "generate[s] considerable data but they are not organized into a form that can be analyzed" (p. 53), or utilized as an "integral part of the program" (p. 56) or the total federal residue control system. This is largely because the current "systems" were not constructed for this purpose. Instead, they have grown in a patchwork way, responding to immediate needs over the years. As a result, there are significant interfacing problems, including an excessive need for manual processing. Other problems include points where needed quality control has not been engineered into the systems, inflexibility and other computer facility inadequacies (hardware and software), and slow feedback to inspection personnel and NRP managers.

b. Options

(1) Complete the information systems development effort begun through the IRM project.

(2) Review and, to the extent appropriate, revise data collection and reporting systems to assure that they provide prompt and accurate feedback on relevant factors, provide adequate information for program analysis and evaluation, and can be utilized as part of an integrated federal residue control system.

c. FSIS Recommendation

While data systems and other IRM needs are being addressed in another chapter, certain options that would help alleviate problems in the IRM and data needs areas were identified in the evaluation of issues concerning residue control. The above identified options should be considered in the Data Systems Recommendations.

10. Open Process

The NAS committee concluded that in the current NRP "priorities are set by a closed process" (p. 57), while in an optimal program:

Priorities should be determined in an open process by using specific, stated guidelines determined largely by considerations of public health. Priorities should be reviewed constantly and changed in accordance with new evidence. [p. 55].

The NAS committee also recommended that open communication between FSIS scientists and outside experts be encouraged (p. 61):

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The program should be developed and operated in a fully open manner, with peer review, continuing and systematic use of advisory committees, public hearings encouraging public participation, and substantial efforts to improve public understanding [p. 56].

a. Agree or Disagree

FSIS agrees that current Agency procedures should be changed to provide greater opportunities for review and participation by outside experts and other interested members of the public and to improve public understanding. In the past, FSIS residue program priorities have been set through a process in which only FSIS personnel, or FSIS personnel in consultation with personnel from other federal agencies, have participated. Currently the joint FSIS-FDA-EPA Surveillance Advisory Team (SAT), established to provide interagency liaison and information exchange, reviews preliminary Agency decisions regarding monitoring and exploratory testing. Some effort is now underway to open this process to public review. For example, in the 1985 Compound Evaluation and Analytical Capability Annual Residue Plan (Blue Book), "FSIS welcomes comments or suggestions" as the compound evaluation system is put into place. Distribution has been so limited, however, that few comments are likely to be elicited as a result. Therefore, when a draft of the new system is submitted to the SAT, FSIS plans to announce its availability in the Federal Register and invite comments.

The degree of openness in other aspects of FSIS residue-related activities has depended on the particular function and how it has been addressed. Participation by the public at large has generally been limited to situations in which regulations are being considered (for example, in recent efforts addressing antibiotic residue problems in young calves and swine). Beginning with the sulfa education campaign about six years ago, industry members and their representatives have played an active role with FSIS and other agencies (ES and FDA) and land-grant universities in developing and implementing residue prevention initiatives, but other members of the public have not been involved. Only recently has there been a commitment to eliciting the views of others who may be able to aid efforts to educate producers in how to avoid residue contamination. Inadequate public information also has contributed to a lack of understanding of this and other aspects of residue control and FSIS's role in the federal system. FSIS's Information and Legislative Affairs staff has been considering how to address public concerns about chemical residues through its information program.

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As this discussion indicates, FSIS believes that a variety of mechanisms may be useful to increase openness and input from outside experts and others. The Agency questions, however, the extent to which additional "systematic use of advisory committees" is appropriate in FSIS programs. The Agency notes that the question of outside scientific review was addressed by the Sub-Cabinet Council Working Group on Food Safety and that the Technical Capability Committee is considering the NAS committee's recommendations in this area.

b. Options

(1) Develop explicit guidelines for determining monitoring and exploratory testing priorities that include regular review in accordance with new evidence; provide for initial and periodic review by the SAT; open the process to public scrutiny and participation by (1) circulating copies of proposals to the Advisory Committee on Meat and Poultry Inspection, scientists, public health officials, industry and consumer representatives, and others with an interest in residue control, (2) holding public meetings on significant issues, and (3) publishing notices and issuing press releases on the results of FSIS and SAT deliberations.

(2) Hold a public meeting at least once a year to discuss the operation of federal residue programs. This meeting would be chaired jointly by appropriate individuals from the involved federal agencies.

(3) Disseminate future editions of the Blue Book more widely by announcing its availability in the Federal Register and through technical publications while controlling printing costs (e.g., by using less expensive paper and a simpler format). This might necessitate handling the Blue Book differently (i.e., no longer printing it through the Program Training Division in Denton, Texas).

(4) Issue expanded reports on the results of residue testing and summarize the results in Food News for Consumers, the Communicator, and the Report to Congress as well as at meetings of the Advisory Committee on Meat and Poultry Inspection.

(5) Seek opportunities to increase the public's understanding of the chemical residue area and to explain in non-technical terms how FSIS's program and the federal regulatory system protect consumers.

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c. FSIS Recommendation

FSIS believes each of these options offers a viable approach to increasing openness and input from outside experts and others. Therefore, the Agency recommends that they all be pursued.

ATTACHMENT A
MEMBERSHIP OF RESIDUE CONTROL COMMITTEE

COMMITTEE CHAIR

Maryln K. Cordle, Deputy Director
Residue Eval. and Plan. Division
Science
Food Safety and Inspection Service

SECRETARIAT

G. Edward McEvoy, Director
Planning Office
Policy and Planning Staff
Food Safety and Inspection Service

Clark Burbee, Section Leader
Food Economics Branch
National Economics Division
Economic Research Service

Patricia Drayne, Deputy Director
Information and Legislative Affairs
Office
Food Safety and Inspection Service

Gary Dykstra, Deputy Associate
Director for Surveillance and
Compliance
Center for Veterinary Medicine
Food and Drug Administration

Basil Eastwood, Program Leader
Dairy Production
Livestock and Veterinary Sciences
Agricultural Programs
Extension Service

Robert Elder, Mathematical Statis-
tician
Statistical Analysis Branch
Mathematics and Statistics Division
Science
Food Safety and Inspection Service

Richard Ellis, Director
Chemistry Division
Science
Food Safety and Inspection Service

William Franks, Chief
Statistical Analysis Branch
Mathematics and Statistics Division
Science
Food Safety and Inspection Service

Henry Hairston, Staff Officer
Inspection Coordination Staff
Regional Operations
Meat and Poultry Inspection
Operations
Food Safety and Inspection Service

Royce Harr, Staff Officer
Program Planning Branch
Residue Eval. and Plan. Division
Science
Food Safety and Inspection Service

Zdenka Horakova, Staff Officer
Evaluation Branch
Residue Eval. and Plan. Division
Science
Food Safety and Inspection Service

Michael Hoffman, Chemist
Program Management Branch
Chemistry Division
Science
Food Safety and Inspection Service

Dixon Hubbard, Staff Leader
Livestock and Veterinary Sciences
Agricultural Programs
Extension Service

William Leese, Asst. Director
Emergency Programs Staff
Meat and Poultry Inspection
Operations
Food Safety and Inspection Service

ATTACHMENT A CONTINUED

Alfred Liepold, Chief
Processed Products Inspection
Procedure Branch
Processed Products Inspection
Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

Earl E. Montgomery, Director
Emergency Programs Staff
Meat and Poultry Inspection
Operations
Food Safety and Inspection Service

Judith Neibrief, Assistant
to the Administrator
Office of the Administrator
Food Safety and Inspection Service

Orville E. Paynter, Senior Science Advisor
Hazard Evaluation Division
Office of Pesticide Programs
Environmental Protection Agency

John Spaulding, Director
Residue Eval. and Plan. Division
Science
Food Safety and Inspection Service

Janet Springer, Deputy Director
Division of Mathematics
Center for Food Safety and
Applied Nutrition
Food and Drug Administration

CHAPTER IV

MICROBIOLOGICAL CONTROL RECOMMENDATIONS

MICROBIOLOGICAL CONTROL RECOMMENDATIONS

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MICROBIOLOGICAL CONTROL RECOMMENDATIONS

A. STATEMENT OF PROBLEM

More than two million cases of bacterial food poisoning occur every year in spite of advanced food processing techniques. Available estimates indicate that meat and poultry products are sources responsible for many food poisoning incidences. It is estimated that in 1981 the problem of Salmonella food poisoning accounted for more than one fourth of all food poisoning outbreaks. Earlier studies have shown that an estimated 30 percent of reported salmonellosis cases involve meat or poultry as sources. FSIS "benchmark" data show that 37 percent of broilers, 5 percent of ground beef, and about 12 percent of the pork sausage sampled contain Salmonella bacteria.

It is generally believed that the incidence of Salmonella food poisoning in humans is on the rise and that the severity of cases is increasing. While the 1984 International Salmonella Symposium concluded that it is not now technologically practical to eliminate salmonella bacteria from the food supply, it should be possible to substantially reduce the existing level.

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B. NAS RECOMMENDATIONS

The recommendations made by the NAS committee are consonant with the themes established in the FSIS Strategic Plan. For instance, the Agency expresses a commitment to improving the effectiveness of inspection and assuring a high degree of public confidence in the meat and poultry supply. These two complementary policy goals are highly dependent on the Agency's success in bringing microbiological contamination under control. The NAS committee also urged FSIS to increase its current efforts to control and eliminate contamination with microorganisms, such as Salmonella and Campylobacter, which cause food-borne illnesses in humans. The committee's recommendation did not contain an explicit list of new programs or procedures. However, the NAS report did offer some suggestions that provide direction to the Agency. Specifically, the committee recommended that an intensified program for microbiological control should include improvements in the following six areas:

1. Increased Laboratory Diagnosis

The Committee recommended that FSIS obtain improved epidemiological data on the incidence of microbiological diseases through laboratory diagnosis of specimens. The results of these analyses could then be used by other agencies, for example, the Center for Disease Control, and the Animal and Plant Health Inspection Service, to control or eliminate microbiological diseases in meat producing animals and birds.

2. Expanded Public Education

The NAS Committee encouraged USDA to expand its public education efforts. Their study specifically identified food industry workers as a group that should be provided with information about hazards associated with improper handling of meat and poultry and practical measures to prevent these hazards.

3. Quality Assurance for Sanitation

The committee recommended that there should be documented assurance, backed by substantial compliance enforcement, of the sanitary wholesomeness of all meat and poultry products.

4. Improved Slaughter and Dressing Procedures

The NAS committee's report stated that the prevention of fecal contamination of the carcass from spillage of gastrointestinal contents or smearing of external fecal matter on the outside of the animals is the single most important aspect of sanitary slaughter and dressing. The report concluded that the contamination level of product leaving slaughtering establishments can be reduced considerably by improved dressing

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procedures to prevent fecal soilage of carcasses and carcass-to-carcass cross-contamination. Thus, the report recommended revised slaughter and dressing procedures that are designed to reduce (or eliminate) fecal contamination.

The report also recommended that there is a need for more careful cleaning and removal of the external surfaces (skin, hair, feathers) from carcass and a need for more enforcement of good sanitation practices.

5. Evaluation or Development of Rapid Diagnostic Procedures

The committee recommended that FSIS evaluate existing rapid diagnostic procedures for detecting microorganisms in meat and poultry, especially species of Salmonella and Campylobacter. The report implied that if the available rapid diagnostic procedures are not applicable to meat and poultry inspection program, the Agency should pursue their development.

6. Surveillance Data

The committee report recommended that FSIS use screening tests or other rapid diagnostic procedures to collect data on the prevalence of microbiological contamination. The report did not say that test results need to trigger regulatory action. Rather, the report recommended that surveillance data be used in any way appropriate to control and eliminate contamination. For example, data from rapid tests might be used to measure the effectiveness to new control programs. Surveillance data could also assist FSIS in (1) identifying contamination sources, (2) setting program priorities, (3) designing new processing procedures, and (4) correlating meat and poultry contamination levels with human food-poisoning levels.

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C. FSIS OBJECTIVES AND STRATEGIES IN THE PROBLEM AREA

NAS Recommendations A and B are addressed by other chapters of this report. FSIS agrees with the NAS recommendation that information and education programs be specifically targeted towards food service and food industry workers. The chapter on Public Education (Chapter IX) includes a recommended program for FSIS. The chapter on Disease Control (Chapter V) recommends that FSIS initiate a small definitive diagnosis activity with the objective of developing and testing associated in-plant and laboratory procedures and other regulatory mechanisms that could be used in a full-blown activity of this kind in the future. This would include microbiological diagnoses as well as other animal diseases. For example, cattle now condemned during ante-mortem inspection for central nervous system disorders could be sampled to determine whether the cause of the disorder was listeriosis.

FSIS has already taken steps to address the recommendation on improved sanitation control. The Agency is now reviewing a draft task force report that recommends a new system for pre-operational sanitation inspection that should provide greater uniformity in inspection and reporting procedures. The new system incorporates sampling procedures and places responsibility for sanitation on the plant, rather than on the FSIS inspector. In practice, the inspector looks at a sample of rooms or equipment from a designated area of a plant. If two items fail, the plant is responsible for recleaning the entire area.

A similar pre-operational sanitation system has already been implemented in poultry slaughter plants by MPI Bulletin 83-13. The task force recognized that it was recommending significant modifications to sanitation inspection procedures now in place in meat slaughter and in the meat and poultry industry. As a result, the task force recommended that implementation proceed gradually and include pilot tests, training and consultation with industry. These activities should commence as soon as staff and funds are available.

The last three recommendations merge to form a program where new methods of control are implemented and then monitored and evaluated using surveillance data collected by rapid diagnostic procedures. FSIS believes that the Agency must find ways to reduce or eliminate microbiological contamination in fresh meat and poultry products and that this control or reduction must take place at the time of slaughter or further processing of these products. FSIS must assure that every slaughter, dressing or processing technique that has strong potential for improved microbiological control is thoroughly tested and evaluated, and, if found to be cost-effective, is implemented. With these goals in mind, the Agency has considered several options that should

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facilitate the development and implementation of new procedures that control contamination. Each option includes (1) a revised, pre-operational sanitation program similar to the one now being reviewed within the Agency, (2) a recommended information and education program, and (3) a small, definitive diagnosis activity.

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D. OPTIONS EVALUATION AND FSIS RECOMMENDATIONS

OPTIONS

1. Option: FSIS would establish microbiological standards for fresh meat and poultry products produced under its jurisdiction. These standards would function as a technology forcing mechanism. For example, the Agency could promulgate standards that would become effective in five years or that would become increasingly stringent over time. The standards would be accompanied by testing and monitoring programs to assure compliance. Fresh product failing to meet the standards would not be allowed on the market. Under this option, the industry would have full responsibility for developing processes that meet the standards.

It is noted that the NAS recommendation referred to microorganisms which cause food-borne illnesses and not total numbers of microorganisms. Thus, this option would envision separate standards for Salmonella, Campylobacter, etc., and not a standard utilizing a total aerobic plate count (APC). It is recognized that (1) some foods may have a high APC and yet not constitute a health hazard, (2) other foods may have a low APC and present a health hazard, and (3) there is no established correlation between the APC's for fresh meat and poultry and the level of any existing Salmonella, Campylobacter, or any other pathogenic organism.

Assessment: Mandatory microbiological standards are currently not viewed as a complete solution for raw meat and poultry products. The 1985 NAS report on "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients" concluded among other things that (1) until changes are made to minimize the infection and contamination of birds on the farm and/or until a method of decontamination is routinely applied to packaged carcasses, it is questionable whether practical microbiological criteria can be set for Salmonella on raw poultry without risk of eliminating poultry as food, and (2) microbiological standards for raw meats will prevent neither spoilage nor food-borne illness and thus do not appear warranted.

The working group of the Codex Committee on Food Hygiene (FAO/WHO, 1979) also concluded that no benefits would result for either public health or quality through the application of microbiological criteria for raw meats, and that application of microbiological criteria for raw poultry would not improve safety.

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Both the NAS and Codex reports are substantially based upon the assumption that raw meat and poultry are properly handled and properly cooked prior to ingestion. The assumption is valid most of the time; however, food associated illnesses continue to affect millions annually, and a high proportion of such illnesses are traced to meat and poultry. Spokespersons for the Centers for Disease Control and the U.S. Public Health Service have indicated that a reduction in the level of Salmonella in the meat and poultry supply would bring about a reduction in human salmonellosis.

The NAS report evaluating criteria also recommended that the Food and Drug Administration (FDA), the Department of Agriculture, the National Marine Fisheries Service, and the U.S. Army Natick Research and Development Center should jointly establish an ad hoc commission on microbiological criteria for foods.

The heads of the involved agencies have approved the concept. FDA took the lead in March of 1985 and representatives from the involved agencies were chosen and met in May of 1985 to discuss the agenda for the commission and the membership. The commission will be charged with determining which foods should be considered for the establishment of standards and what criteria should be adopted.

While it is recognized that mandatory microbiological criteria will not completely resolve the microbiological safety problems associated with raw meat and poultry products, the levels of Salmonella and other pathogens present appears to be lowest where the corporate processing, sanitation and quality control procedures are the best. Processors with marginal capabilities in these areas generally have the highest level of pathogens. Therefore, some portion of the level of pathogens in raw meat and poultry relates to plant practices. FSIS may develop some form of microbiological criteria to assist in eliminating correctable deficiencies. The use of non-mandatory microbiological criteria combined with HACCP systems is a viable modification of this option.

2. Option: FSIS would continue its cooperative research program with the Agricultural Research Service (ARS) and would initiate programs to create an environment where there would be sufficient economic/market incentives for plants to voluntarily implement the best processes available for controlling microbiological contamination. The Agency would collect the data necessary to evaluate the success of the voluntary reduction and control efforts that industry initiates. FSIS would support the evaluation and

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verification of new rapid diagnostic procedures and would work with industry to evaluate all new slaughter, dressing and processing procedures that appear to have potential for controlling microbiological contamination.

Assessment: There are many positive aspects to the second option. Microbiological control is one area where the cooperative research program with ARS has been most successful. Research to answer questions in microbiology has been fruitful, and the Agency's highest research priority, the control of Salmonella and Campylobacter in meat and poultry products, is being actively pursued by three ARS field laboratories. However, the issues raised by the Committee on Research are relevant here. For example, FSIS must take a more active role in the development and evaluation of rapid tests that show promise. That may require some reprogramming of funds.

In the area of regulatory policy, FSIS believes that the inspection program should not add any unnecessary impediments to the efficiency and productivity of the manufacturing process and that each firm should have the flexibility to develop its own system for controlling microbiological contamination. In general, it follows that the Agency prefers performance standards to regulations that require specific types of equipment or specific types of procedures. However, if a cost-effective procedure for microbiological control were available, the Agency would not hesitate to require its implementation.

In the area of market incentives, FSIS is attempting to create an environment where there are incentives to develop and use the latest technology to control contamination. FSIS has already publicized the fact that the Agency is looking at incentive concepts and is currently examining the possibility of allowing product labels to communicate control programs that go beyond regulatory requirements.

3. Option: FSIS would aggressively pursue the development of new slaughter and dressing procedures that control or reduce contamination. At the same time FSIS would look for methods that would "pasteurize" fresh meat and poultry products. When cost-effective methods or procedures were identified, the Agency would assure that they were used. The Agency would actively work with industry to test and evaluate any new process or procedure with potential. If additional methods development activities were required, the Agency would take the necessary steps to assure that these activities were initiated.

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Assessment: The fundamental difference between Option 2 above and this option is that under Option 2 the Agency would assume a supportive, passive role as opposed to an active, aggressive role. This option is based on the conclusions that (1) the microbiological contamination problem can only be solved at the slaughter/processing stage of production and it is, therefore, FSIS' problem to solve, and (2) if FSIS does not take an active role in all aspects of this area, it is doubtful that any applicable technological advances will occur.

There are elements of the existing program that fit this option. For example, the Agency is moving to control dressing procedures through its program for modernizing meat and poultry inspection. FSIS has implemented new poultry slaughter inspection procedures and is currently testing similar new procedures for cattle and swine that put more responsibility on plant personnel to detect and correct carcass deficiencies through quality control programs that the government inspector monitors. As part of these new procedures plants develop quality control plans that (1) identify Critical Control Points (CCP) in the slaughter/dressing process, (2) identify potential problems that could occur at each critical control point, and (3) specify the corrective action that the plant will take for each problem.

The plants then assume responsibility for correcting processing defects such as external fecal matter, hair and bruises. Obviously, many of the processing or manufacturing defects are associated with microbiological contamination. Under these new procedures, FSIS will monitor the plants' performance in controlling defects. Failure to meet certain Finished Product Standards (FPS) means that a particular piece of equipment, e.g., a hidepuller, or a dressing procedure is out of control and must be corrected or adjusted. In this way the FPS functions as an indirect control on equipment and dressing procedures.

In tests thus far, the inspection staff involved have agreed that carcasses look cleaner, and although no microbiological data is available, the Agency believes that carcasses that appear cleaner generally do have lower levels of contamination. However, as discussed earlier, low numbers of microorganisms and safety are not necessarily directly related. Still, the Agency anticipates that the new slaughter procedures will reduce the organisms that cause food-poisoning in humans. The Agency can also depend on the new slaughter procedures to increase inspection efficiency, and that will free up resources that can be applied to other areas of the microbiological contamination problem.

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The Agency believes that the implementation of the new slaughter procedures responds to the NAS recommendation to revise slaughter and dressing procedures and that the application of quality control principles to slaughter inspection should improve the overall performance of the slaughter and dressing process. The Agency recognizes, however, that the new inspection procedures are only designed to control visible contamination such as fecal matter and hair. Whether or not they reduce total microbiological contamination, they are consistent with overall Agency objectives of focusing more resources on public health problems and shifting responsibility for product quality to industry.

In another area, FSIS is currently actively involved in ongoing research for rapid diagnostic tests and uses staff resources to evaluate promising new procedures. This responds to the NAS recommendation that FSIS should pursue the development of rapid diagnostic procedures if adequate tests do not currently exist.

FSIS Recommendations

FSIS convened a committee to review the recommendations in the NAS report that pertained to microbiological controls. The committee was made up of seven members, five of whom were from different representative units in FSIS, one from the Centers for Disease Control, U.S. Public Health Service, and one from Agriculture Research Service, USDA.

The committee members reviewed those areas in the NAS report that concerned microbiological issues or recommendations. Meetings and/or telephonic discussions were held and options were prepared to outline the major methods that could be used by FSIS to implement the intent and the recommendations of the NAS report. The committee recognized that the report and its microbiological control recommendations are extensive, are not specific mandates, may require additional funds and cannot be accomplished instantaneously. They are best characterized as a strategic managerial philosophy to be implemented as soon as possible and to guide the future pathway of FSIS in the area of microbiological controls.

Although the material presented in the NAS report is extensive, the committee derived three options or methods which it could use to respond; these are summarized as follows:

- o Use microbiological criteria which could include legal microbiological standards, microbiological guidelines to complement quality control programs, and microbiological specifications for purchasing.

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- o Stimulate methods development aimed at reducing microbial hazards, reducing the level of pathogenic bacteria in food, and extending shelf life. In addition, this option would encourage voluntary implementation of the fruits of this methods development by the meat and poultry industry.
- o Aggressively pursue the development of new slaughter and dressing procedures or processes to control or reduce microbial contamination and therefore minimize dissemination in subsequent points of usage including the home.

The committee determined that the scope of the options is very broad and that there are areas in FSIS' responsibilities which could benefit from each of the options described. In general, the majority of the FSIS response will be in accord with option three, that is, to develop efforts to reduce microbial contamination at the initial source of slaughter and dressing. This is an area that has been neglected for decades but which is now targeted for intensive efforts.

The methods development and economic incentive measures of option 2 cannot be neglected; instead, they are likely to be necessary as an adjunct to implementation of the desired improved slaughter and dressing procedures. The methods development option would also play a major role in prepared meat and poultry products where it is important to destroy many pathogenic bacteria and to render products which are "ready to eat" commercially safe. Although a major effort in the area of microbiological criteria is neither warranted nor recommended by the committee, specific situations now exist or may develop where this option would be beneficial to FSIS. Currently, the Wholesomeness Meat Act and the Poultry Products Inspection Act require that products be safe and wholesome. FSIS has interpreted this provision to mean that "ready to eat" products must be free of harmful bacteria such as Salmonella. This interpretation is clearly a microbiological standard which is beneficial and will be continued. It is also likely that microbiological guidelines (targets) may become the most effective means of monitoring the operating effectiveness of new slaughter and dressing equipment and technology as well as for verification of controls at critical control points.

This response will most likely require some increased funding for (1) testing and evaluating rapid diagnostic procedures, (2) exploring new control methods, (3) working with plants to test and evaluate new slaughter, dressing and processing procedures, and (4) monitoring the effectiveness of new voluntary control programs. These funds could come from reprogramming following the NAS study on the risk assessment of poultry inspection.

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Although the implementation of these recommendations by FSIS may take some additional resources, eventually they should reduce costs for both industry and government. The revised procedures will incorporate Hazard Analysis Critical Control Point (HACCP) principles that should lead to improved cost-effectiveness.

The HACCP concept is an effective and rational approach to the assurance of safety and to the prevention or delay of spoilage in foods. In some cases, monitoring of CCPs can be accomplished through the use of physical and chemical tests, visual observations and sensory evaluations.

MICROBIOLOGICAL CONTROL RECOMMENDATIONS

COMMITTEE CHAIR

Jerry Carosella, Deputy Director
Microbiology Division
Science
Food Safety and Inspection Service

SECRETARIAT

Loren Lange, Deputy Director
Policy and Program Planning Staff
Food Safety and Inspection Service

Leroy Blankenship, Research Leader
Russell Research Center
Agricultural Research Service

Morris Potter, Veterinary Epidemiologist
Bacterial Zoonosis Activities
Centers for Disease Control
Department of Health and Human Services

Eduardo Ramos, Staff Officer
Slaughter Inspection Standards and
Procedures Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

Michael Rose, Branch Chief
Sanitation Standards and Review Branch
Facilities, Equipment and
Sanitation Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

Douglas Swacina, Staff Officer
Inspection Coordination Staff
Regional Operations
Meat and Poultry Inspection
Operations
Food Safety and Inspection Service

CHAPTER V

DISEASE CONTROL RECOMMENDATIONS

DISEASE CONTROL RECOMMENDATIONS

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DISEASE CONTROL RECOMMENDATIONS

A. STATEMENT OF PROBLEM

The NAS committee believes that the inspection of every animal to identify gross lesions and other signs for the purpose of making carcass disposition decisions is an inefficient way of protecting public health. They say that inspection should focus more on the control of infectious agents in meat and poultry to prevent their occurrence.

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B. NAS RECOMMENDATION

Develop definitive diagnoses on a random sampling of retained and condemned carcasses to develop incidence data and to use for training purposes. Incidence data can be used for preventing the disease earlier in the animal production chain. Material from definitive diagnoses can be used for pathology correlation sessions as continuing education for in-plant veterinary medical officers.

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C. FSIS OBJECTIVES AND STRATEGIES IN THE PROBLEM AREA

The FSIS Strategic Plan for the next five years reflects the Agency's commitment to move to more efficient inspection processes and to maintain or improve the current standard of consumer protection. Changing the inspector's focus from a sorting to a monitoring mode and shifting the sorting task to industry under quality control mechanisms monitored by the government could increase the efficiency of inspection and, at the same time, at least maintain, if not improve, the effectiveness of the Agency's enforcement system because of its preventive orientation. As new systems are developed and the capability for animal identification systems becomes available, the data generated by the Livestock and Poultry Disease Reporting systems will become valuable in designing systems which will prevent and control diseases.

The issue FSIS faces is not whether it wants to move in this direction in the future; it is how to move in this direction without reducing public confidence in its ability to assure the safety of the meat and poultry supply and without disrupting production and marketing processes. There is little doubt that a definitive diagnosis activity will be necessary to support a preventive enforcement system. One issue is whether or not a definitive diagnosis activity or prevention and control of animal disease are within the scope of the Federal Meat Inspection Act (FMIA). These activities, while desirable in and of themselves, do not appear to be included in the FMIA, so FSIS must consider how agencies can work together on this problem.

In addition, FSIS needs to make its decision about when and how to adopt a definitive diagnosis activity within a framework of program modernization that requires the scheduled implementation of a whole set of activities, some of which are complementary to, or even necessary for, disease control. In this sense FSIS needs to think about a definitive diagnosis activity in its relationship to other activities such as animal traceback and serological testing. For example, can definitive diagnoses be effective in preventing disease without a system for animal ID and traceback? Can animal-by-animal organoleptic inspection be reduced without a substitute such as serological tests? With these kinds of issues in mind, FSIS has evaluated the following options with respect to undertaking a definitive diagnosis activity.

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D. OPTIONS EVALUATION AND FSIS RECOMMENDATIONS

OPTIONS

1. Maintain Status Quo. Agency does not presently do definitive diagnoses on retained or condemned animals, except where the analysis to support a finding as to the existence of abnormal tissue happens also to produce a definitive diagnosis. There is no laboratory capability in the Agency for the animal/microbiological or the toxicological analyses that would be necessary to do definitive diagnoses. The Agency does not need definitive diagnoses to make carcass dispositions.
2. If new money can be obtained to build the necessary laboratory capacity, immediately initiate a moderate definitive diagnosis activity with the objective of developing and testing associated in-plant and laboratory procedures and other regulatory mechanisms that could be used in a greatly expanded activity of this kind in the future. Examples of other elements that could be tested are: how the data collected would be used to improve animal disease reporting; how the data collected would be used for inspector education; what regulatory mechanisms could be used to assure that information generated is used to control disease earlier in the animal production chain.
3. If new money cannot be obtained to build the necessary laboratory capacity, immediately initiate a small definitive diagnosis activity with the objective of developing and testing associated in-plant and laboratory procedures and other regulatory mechanisms that could be used in a greatly expanded activity of this kind in the future.
4. Plan to initiate a definitive diagnosis activity when certain other complementary activities are expected to be underway and/or when resources are released from other activities to support building the necessary laboratory capacity.

FSIS RECOMMENDATION

FSIS has selected Option 3. Although definitive diagnoses are not necessary in our present inspection procedure, the Agency believes it is reasonable to expect that such an activity can help us become more effective and efficient in controlling disease conditions in the future. In fact, the Agency is now helping to support an activity being conducted by the Extension Service with three universities to explore what type of definitive diagnosis data can be generated in plants where

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inspection is taking place, the mechanism for recording and feeding back diagnostic data to feedlots and veterinarians, and whether the improved information will, in fact, improve herd health management.

If results from the Extension Service study show that a definitive diagnostic activity appears to be effective, FSIS is receptive to using whatever laboratory capability it can spare to start a pilot program of its own to further explore the feasibility of integrating a definitive diagnostic activity into its inspection systems. By the time the Agency is ready to initiate a pilot program, it is likely that some of the complementary mechanisms such as animal identification systems and improved data automation will be available to facilitate program implementation.

The success of this pilot program will determine whether new funds or funds from less productive inspection procedures should be used for the increased laboratory capability that would be necessary to support a greatly expanded definitive diagnostic activity.

ATTACHMENT A
MEMBERSHIP OF DISEASE CONTROL COMMITTEE

COMMITTEE CHAIR

Douglas Berndt, Director
Slaughter Inspection Standards and
Procedures Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

SECRETARIAT

Judith Segal, Director
Policy and Planning Staff
Food Safety and Inspection Service

Barbara Balsley, Staff Officer
Slaughter Inspection Standards and
Procedures Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

Dixon Hubbard, Staff Leader
Livestock and Veterinary Sciences
Agricultural Programs
Extension Service

Lonnie King, Principal Staff Officer
Laboratory Support
Animal Health Program
Veterinary Services
Animal and Plant Health Inspection Service

Jack Leighty, Director
Pathology and Epidemiology Division
Science
Food Safety and Inspection Service

Morris Potter, Veterinary Epidemiologist
Bacterial Zoonosis Activities
Centers for Disease Control
Department of Health and Human Services

ATTACHMENT A - Continued

Jane Robens, National Program Leader
Food Safety and Health
National Program Staff
Agricultural Research Service

Tanya Roberts, Agricultural Economist
Food and Agricultural Policy
National Economics Division
Economic Research Service

CHAPTER VI

ANIMAL IDENTIFICATION AND TRACEBACK RECOMMENDATIONS

ANIMAL IDENTIFICATION AND TRACEBACK RECOMMENDATIONS

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ANIMAL ID AND TRACEBACK RECOMMENDATIONS

A. STATEMENT OF PROBLEM

Contamination on the farm in the form of residues and meat-borne pathogens creates a significant problem that is difficult for the inspection system to control by traditional inspection methods. Once animals reach the slaughterhouse, the line speeds and economic concerns permit sampling for residues on a very limited basis, and mostly with technology that is still quite imperfect and is not yet adequate to alleviate the problem. While the prevention of theft and the control of certain animal diseases has led to the limited application of various animal identification and traceback techniques, little effort has been made to apply these techniques to the problem of residue control and the prevention of zoonotic diseases.

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B. NAS RECOMMENDATIONS

In its 1985 report on the scientific basis of the Nation's meat and poultry inspection program, the National Academy of Sciences (NAS) recommended that an animal identification system "be created to allow diseased or contaminated animals to be traced to their source, to increase the farmer's share of responsibility for contamination, and to facilitate epidemiological studies of specific disease outbreak." It further recommended that the identification system be used in conjunction with an integrated USDA animal surveillance program using data from meat and poultry inspection "to ensure that FSIS routinely trace disease and chemical contamination back to their source." To the NAS, a traceback and recall system for all animals and products from the producer to the final sale forms an essential part of an "optimal meat and poultry inspection program."

ANIMAL ID AND TRACEBACK RECOMMENDATIONS

C. FSIS OBJECTIVES AND STRATEGIES IN THE PROBLEM AREA

At the present time, FSIS deals with the problem of pathogens and chemical residues in animals after they have entered the slaughterhouse. Through the process of organoleptic inspection, unsafe product is identified and removed from the food chain. In the case of gross pathology, the primary drawback of the present system of inspection for pathogens is that it does not contribute to the prevention of these conditions in the future. Therefore, it is a relatively inefficient way to prevent unhealthy livestock from entering the food supply. Further, it tends to limit the speed at which animals can be processed. In the case of residue screening, product which has been sampled and found by the laboratory to be positive for chemical contamination will have moved into commerce before the results are returned to the point of origin. However, these results can be used to develop trend data and to alert inspectors to potential problem producers, provided the sources of the contamination is known.

Part of the Agency's future agenda as reflected in its Strategic Plan, is to move into more productive forms of inspection. FSIS is planning to direct more intensive efforts to the control of microbiological and chemical contaminants in meat and poultry. These efforts would include the generation of epidemiological data that could be fed back into the animal production chain to improve the condition of animals presented for inspection. An animal identification and traceback system would be needed to carry out this kind of inspection activity. FSIS believes that the institution of a national livestock identification system can yield significant benefits to all groups involved in the production, distribution, and consumption of meat and poultry. Federal and State animal health authorities would be able to trace animals to their source when appropriate action needed to be taken to prevent epizootic infections or chemical residues or other contamination. Benefits would also accrue to producers in the form of reduced herd morbidity and mortality and as a tool in the development of better animal husbandry. By monitoring the results of breeding improvements from the farm to the slaughterhouse, producers, consumers, and food companies could all be expected to benefit from the enhanced livestock quality that animal identification and traceback could bring. In addition, effective animal identification can deter theft and thereby reduce losses to producers and insurers. Therefore, it is the opinion of FSIS that the NAS recommendations have sufficient merit as to warrant serious consideration of the various options available to FSIS and USDA is producing such a system.

D. OPTIONS EVALUATION AND RECOMMENDATIONS

OPTIONS

The agency has identified four major options for dealing with the problems outlined in the NAS report.

1. Option: Liaison with the Responsible State and Federal Agencies

The present system of inspection relies on the Animal and Plant Health Inspection Service and various State agencies to deal with documented, high rates of animal pathology. The Food and Drug Administration and/or the Environmental Protection Agency are the Federal agencies responsible for investigating high rates of chemical contamination.

Assessment: None of these organizations have the type of animal identification and traceback system in effect that would meet the concerns outlined in the NAS report. Therefore, the current system is not capable of identifying and tracing 100 percent of the animals found to be violative to their points of origin.

2. Options: Utilize Current State Systems of Identification

At the present time, several States have various types of animal identification and traceback systems in operations. Under this option, FSIS would work with those States to standardize their techniques and procedures and to exchange information in an effort to improve the current nationwide average of 70 percent effectiveness in animal ID and traceback. FSIS could also assume a lead role in coordinating the development of a set of voluntary standards and procedures for animal identification that could be used by States that currently do not have any systems in operation.

Assessment: Option 2 represents a relatively low cost approach to raising the current levels of effectiveness in identifying and tracing animals, which could be implemented at the direction of the FSIS Administrator. The cost would be limited to one staff year plus overhead to initiate contract and cooperative activity with various States. Since there is already strong support for animal ID by some producers and in some segments of the meat industry, this option could be very effective in bringing more animals under some form of identification system.

ANIMAL ID AND TRACEBACK RECOMMENDATIONS

3. Option: Mandatory 30-Day Ownership Certification

This option could be used alone or in conjunction with other options as a starting point for a standardized nationwide system of tracing animals to their points of origin. The system would begin by establishing a regulation that required slaughter plants to maintain records on the ownership of all swine for a 30-day period immediately preceding slaughter. Later, this system could be applied to other animals as appropriate and expanded into a system for tracing all animals to their farms of origin.

Assessment: Option 3 could be put into operation with little difficulty and may be generally acceptable to producers and slaughter plants. It would provide an excellent, low cost, and highly effective start-up program for a nationwide system for tracing animal ownership. Its primary value would be in establishing the means for tracing animals with violative levels of residues to their previous owners. Its primary drawback would be in the opposition to this proposal that could arise from buying stations, auction houses, and marketing people in general who would be concerned about having to absorb possible losses for rejected product.

4. Option: Mandatory Nationwide System for Livestock Identification

This option proposes that establishment of a uniform, mandatory, national system of livestock identification to be administered by the Federal Government under the auspices of the USDA. The actual identification of the animals would be carried out in any one of several ways (ear tattoos, metal tags, back tags, electronic implants, or serological profiles) depending on the technology and funding available at the time of implementation. The system might be phased in using a proven means of identification such as back tags and eventually move to a more sophisticated technology such as implanted electronic transmitters, transponders or computer chips, when the technology has matured. Under this plan, the USDA would assume the lead in developing the overall program, including the regulations and procedures as well as actual systems to be used.

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Assessment: Option 4 could be implemented under existing USDA statutes. It would be the most effective of all the approaches discussed above, particularly in providing the accurate and efficient traceback capability that is essential to the improved disease and residue control that is prescribed by the National Academy of Sciences. Implementation of a nationwide, uniform, and mandatory identification system would provide advantages to all those concerned with the marketing of animals and animal products. A multipurpose data base could be created that would show the locations and characteristics of herds in all regions of the country. The development of such data could lead to better name recognition for farmers and firms involved in the production of top quality livestock. However, this approach would also be the most expensive to implement and the one most likely to encounter strong interest group opposition from auction houses and marketing people who would fear losses associated with rejected product. In fact, the costs of this proposal cannot be quantified until the procedures have been outlined and identification system selected. Small incremental steps could be taken which would avoid massive up-front costs. A feasibility study could be funded at the outset while industry and government met to discuss the details of the overall proposal.

FSIS RECOMMENDATIONS

Because of the potential merit in establishing a national system of animal identification and because renewed interest has been expressed by such groups as the American Meat Institute, the National Pork Producer's Council, and the National Academy of Sciences, it is an opportune time for USDA to reconsider the establishment of such a system. The USDA Office of General Counsel has determined that a uniform, national system could be mandated under the existing statutes. A comprehensive system established under the existing statutes would be administered under the shared authority of several agencies, including FSIS, APHIS, and the Food and Drug Administration. Therefore, FSIS recommends the adoption of Option 4 which would incorporate the activities outlined under Option 3, e.g., requiring slaughter plants to maintain records on the ownership of all swine for a 30-day period immediately preceding slaughter. Option 4 would entail the following steps for implementation:

1. The Department of Agriculture should begin at once to develop a program that would require the mandatory, uniform, national identification of the ownership of swine and the maintenance of these records by slaughter plants. Once the program has been demonstrated to be practical and effective, it could be extended to include additional species.

ANIMAL ID AND TRACEBACK RECOMMENDATIONS

2. A Notice of Intent to Regulate should be published in the Federal Register enumerating the benefits to be derived from a national animal identification system. The Notice should invite comments from all interested groups in Government, industry, and the general public. Detailed information should be solicited on possible approaches to identification including physical devices, economic impacts, and advantages and disadvantages of various ID systems.
3. The view of all major interested parties should be solicited in letters to be mailed to industry organizations, the heads of Government agencies -- including the Departments of Agriculture -- professional associations, and consumer groups.
4. A working group should be convened within the Department to develop a specific implementation plan for uniform national livestock identification that would be embodied in a formal rulemaking. In addition to determining what type of system should be established to identify animals, the group should identify recordkeeping requirements, IRM needs, necessary staffing, and the specific role of the States in the system's operation. The working group's composition should include USDA officials (APHIS, FSIS and Packers and Stockyards) and members from other affected federal agencies. It would also be desirable to include representatives from industry and consumer groups and constitute the working group as an Advisory Committee. The intent to form a working group and its proposed membership should be announced in the Federal Register.

ATTACHMENT A
MEMBERSHIP OF ANIMAL ID AND TRACEBACK COMMITTEE

COMMITTEE CHAIR

G. R. Snyder, Senior Staff Officer
Slaughter Inspection Standards and
Procedures Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

SECRETARIAT

Charles Danner, Director
Planning and Coordination Unit
Planning Office
Policy and Planning Staff
Food Safety and Inspection Service

Ronald D. Cipolla, Assistant General Counsel
Regulatory Division
Office of the General Counsel

Jack Leighty, Director
Pathology and Epidemiology Division
Science
Food Safety and Inspection Service

Leroy W. Schnurrenberger, Chief
Staff Veterinarian
Swine Diseases and Epidemiology
Special Diseases Staff
Veterinary Services
Animal and Plant Health Inspection Service

John E. Spaulding, Director
Residue Eval. and Plan. Division
Science
Food Safety and Inspection Service

Cecil R. Watson, Chief Staff
Veterinarian
Animal Identification and Surveillance
Interstate Inspection and Compliance
Veterinary Services
Animal and Plant Health Inspection Service

Charles Williams, Writer Editor
Executive Correspondence and
Special Assignments Staff
Information and Legislative Affairs
Food Safety and Inspection Service

CHAPTER VII

DATA SYSTEMS RECOMMENDATIONS

DATA SYSTEMS RECOMMENDATIONS

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DATA SYSTEMS RECOMMENDATIONS

A. STATEMENT OF PROBLEM

As a regulatory agency, the Food Safety and Inspection Service (FSIS) must make management decisions based upon timely and accurate information obtained from the inspection workforce and other sources. Where data is inappropriate, incomplete or not timely, the decision-making process is compromised. The problems identified with existing FSIS data systems can be categorized into five areas:

- o Data which is not collected but should be.
- o Inadequate organization and management of data.
- o Limited access to, use of, and analysis of data.
- o Below-optimal levels of automation and computerization.
- o Lack of a timely and accurate data collection process.

The quality, timeliness, and usefulness of data must be improved to support the management of the inspection activities. From a budgetary and personnel standpoint, the resources allocated to information management are not adequate to meet the needs of the Agency. In addition, the organizational structure used to manage information in the major program areas requires evaluation in light of current Information Resources Management (IRM) requirements and the expanded use of microcomputers.

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B. NAS RECOMMENDATION

The report from the National Academy of Sciences (NAS) proposes a heightened use of data currently residing in Agency data bases, as well as the addition of other information. In order to improve the efficiency and effectiveness of inspection, the NAS recommends that FSIS veterinarians and management staff obtain increased access to information on meat-borne hazards, animal diseases, residue violations, and other related items.

The first step toward accomplishing this goal would require modifications to the design of several existing computer systems to allow easier access to data and to provide information in a more usable format. The benefits of redesign would allow the inspection program to accomplish such tasks as allocating inspection resources based upon risk, modifying the intensity of inspection based upon plant, regional, or seasonal characteristics, and tracking animal diseases and residue violations more effectively.

A second recommendation is to upgrade the overall data analysis capabilities which exist in the Agency. In terms of personnel, this would require: (1) improving the systems design and analysis capabilities in the IRM area, and (2) increasing the quality and number of management and program analysts with the skills to design and interpret analytical studies in the evaluation of program effectiveness. The NAS report also advocates: (1) upgrading FSIS minicomputer/mainframe capabilities, (2) increasing the use of microcomputers, (3) improving communications and computer-assisted information transfer, and (4) examining the potential for increased laboratory automation.

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C. FSIS OBJECTIVES AND STRATEGIES IN PROBLEM AREA

The Agency recognizes that it is not making optimal use of the information which is available. In the past, large amounts of data were collected for statistical purposes to report to Congress on the scope of operations; data were not used for analytical purposes, for evaluating program effectiveness, or for improving the day-to-day quality of inspection in the plant. For this reason, FSIS has established very clear policy goals in its Strategic Plan which, when implemented, will provide the kinds of capabilities that are needed to gather, store, and quickly analyze inspection program information. Therefore, the Agency is in complete agreement with the NAS recommendation that it must improve the collection, management, use, and analysis of FSIS data to accomplish the objective of making maximum use of the data that is currently available.

Many of the recommendations proposed by FSIS would result in increased demands upon the computer resources in the Agency. Until all of the Agency's requirements are identified, it is not possible to consider them on an individual basis. Rather, the goal of this analysis is to develop a framework in which current and future needs can be met in a timely and accurate manner.

Taken together, the recommendations in Subpart D provide an infrastructure in which timely and accurate data may be accessed by management and program analysts in the decision-making process. In brief, this will require: (1) additional staffing for programmers, systems analysts, management analysts, and program analysts, (2) a reorganized information system to link appropriate data bases, (3) upgraded centralized computer facilities in Washington and certain field offices, (4) and microcomputers for the inspection workforce.

D. OPTIONS EVALUATION AND RECOMMENDATIONS

Many of the recommendations in the NAS report which impact on data systems are addressed by other FSIS recommendations which discuss specific program elements, such as animal identification. The goal of this study was to find the best infrastructure to meet those present and future IRM needs identified by FSIS program offices. Accordingly, the options discussed here concentrate on the mechanics of placing such a system into effect, rather than addressing individual data system requirements. The options considered by the Data Systems Task Force fall into four areas.

In Area 1, the options address ways to increase the number of computer professionals with the skills and expertise required to create a data system which can support analytical studies. Area 2 addresses the need for an increase in the number of management and program analysts with the skills to design, perform and interpret those analytical studies. The third area sets forth possible data base frameworks which could provide a flexible, accessible and easy-to-use system. This area concentrates on upgrading the computing facilities in Washington, D.C., and the regional offices. Area 4 addresses the need for timely and accurate data by looking at various data collection methods.

AREA 1: Improve programmer and systems analyst capabilities in the design of agency data bases.

OPTIONS

1. Option: Increase staffing and rely totally on in-house expertise rather than contracting with outside consultants.
2. Option: Increase staffing and in-house expertise, and allow major program areas to augment with consultants as needed for specific projects.
3. Option: Increase staffing and in-house expertise, and contract at the Agency level for a multi-year Basic Ordering Agreement (BOA) to provide technical consultants for all major program areas.

DISCUSSION

Although it would be desirable to maintain a self-sufficient in-house staff for continuity and uniformity in systems design, the reality is that FSIS is now, and will in the future be, unable to attract and retain the required number of computer professionals. Increasing the size and expertise of the

DATA SYSTEMS RECOMMENDATIONS

Agency's computer staff is necessary, but the computer staffs will still need to be augmented with outside consultants. A BOA is the preferred approach for several reasons: (1) a single pool of consultants will enhance coordination among different data base systems, (2) staffing can be augmented in a quicker and more efficient manner, and (3) the orientation delays associated with "new" consultants is reduced for each new project.

FSIS RECOMMENDATION: FSIS recommends the adoption of Option 3.

AREA 2: Improve management and program analyst capabilities for the interpretation of data in the management decision process.

OPTIONS

1. Option: Increase staffing to develop in-house analytical expertise.
2. Option: Increase staffing for in-house analytical capabilities and use consultants as needed for specific projects.
3. Option: Increase staffing for in-house analytical capabilities and use a multi-year Basic Ordering Agreement to augment in-house capabilities.

DISCUSSION

In the short term, the use of a BOA has the same advantages for management and policy analysis as it does in the design of computer systems. However, in the long run, it is imperative that the agency develop its own analytical capabilities to the point where the use of a BOA is largely unnecessary. Such expertise will be familiar with the day-to-day operations of the organization and will provide a level of continuity that should not be provided by a contractor. In addition, it is more important for the agency to exercise control over the use and interpretation of information in carrying out its regulatory mandate than the development of data base systems.

FSIS RECOMMENDATION: FSIS recommends the adoption of Option 1.

AREA 3: Improve the quality of information and its accessibility by FSIS managers.

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OPTIONS

1. Option: Data base systems are developed and maintained as separate entities. Data bases may contain data in incompatible formats and information might not be transferable between systems. In this decentralized approach, each program has responsibility for data input, data quality, data analysis, and systems design.
2. Option: Data base systems remain separate, yet function as satellite systems attached to a single central data base in a totally integrated data base environment. Systems must meet basic rules, standards, and conventions developed by a central IRM entity. With this centralized direction, each major program area retains responsibility for data input, data quality, data analysis, and systems design.
3. Option: All data base systems are designed and implemented by a central IRM entity. In a centralized system, each major program area retains responsibility for data input, data quality, and data analysis, but control of the data base system programming is relinquished.

DISCUSSION

The current data base environment is decentralized; in general, FSIS data bases are neither linked nor compatible with each other. This approach fails to provide the coordination in which computerized information from different program areas can be shared for decision-making. In contrast, an integrated data base environment would leave responsibility for data quality with the program area where the expertise resides, yet implement commonality between appropriate data bases so that information could be shared among functional areas. This would place the oversight and standardization function with a central IRM entity, while systems design would remain the responsibility of those offices that need and use the data. Under the third option, all systems design and programming is conducted by a central IRM entity; the result is a trade-off between systems efficiency and data quality. The technical aspects of programming are improved, but the programmers lose some understanding of the meaning of the information they are working with. Given the mission of the agency, the emphasis should be placed on ensuring that data is of the highest quality for use in making management decisions, even at the expense of some programming efficiency.

FSIS RECOMMENDATION: FSIS recommends the adoption of Option 2.

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AREA 4: Improve the collection and timeliness of data.

OPTIONS

1. Option: Retain primary responsibility for data capture and integrity at the current central collection sites. Provide additional staffing to adequately monitor the quality of the data.
2. Option: Transfer primary responsibility for data capture and integrity to the field offices (e.g., Region or Area). Provide necessary equipment, telecommunications, and staffing at these intermediate sites.
3. Option: Transfer primary responsibility for data capture and integrity to those points closest to the information source (e.g., IICs, Circuit Supervisors, field laboratory personnel). Provide necessary equipment and telecommunications at these points.

DISCUSSION

Given the current method of collecting and disseminating information to and from the field inspection workforce, the data used in decision-making could be improved by increasing the staff devoted to data verification. This is the simplest solution but is a band-aid approach. To achieve a more permanent impact on data quality and timeliness, a different approach would be to shift the responsibility for the data closer to the source of the data. For example, data entry and verification functions could be shifted from the Des Moines Data Center to the field, most likely the Area Office. This initiative could be taken one step further by assigning ownership and placing the responsibility for the data with the "data originator" (e.g., IIC, Circuit or IFO Supervisor, laboratory personnel), thereby further improving the quality and timeliness of the data. This could be accomplished by providing microcomputers and uniform software at the inspection data collection locations and by increasing laboratory automation. Further efficiencies and productivity gains would also be realized as other agency operations are enhanced through the use of microcomputers. This would be consistent with the agency's goal to automate existing recordkeeping systems which are geared to determining plant compliance, performance history and required corrective actions.

FSIS RECOMMENDATION: FSIS recommends Option 3. For this option to be implemented, it must be accompanied by either Option 2 or Option 3 in Area 3.

DATA SYSTEMS RECOMMENDATIONS

E. ORGANIZATION AND RESOURCE IMPLICATIONS OF RECOMMENDATIONS

Two points in the recommendations merit emphasis. First, the FSIS central computing facility in Washington must be upgraded to accommodate increased telecommunications and processing workloads. The facility will house an integrated data base environment which will electronically link all appropriate agency data bases. Second, in order to improve the timeliness and accuracy of data, the responsibility for data entry should reside at the point where information is initially collected. This will require the use of computers in the Regional Offices, field laboratories, and down to the level of the Inspector-In-Charge (IIC).

To accomplish these objectives, changes in staffing and office duties will affect various organizations. Offices in the major program areas will continue to design systems and retain responsibility for data quality. In addition, to achieve an integrated data base environment, during a phase-in period, these offices will have to make necessary modifications to existing systems so that they can tie-in with a central data base. The major program areas will also provide hardware and software support to their personnel in the headquarters and field offices, and will monitor task orders under the BOA. These responsibilities will necessitate the placement of computer programmers and systems analysts in the program areas.

A central computer staff will have responsibility to operate the central computer facility, maintain a central data base which all appropriate program office data bases will tie into, and monitor an agency-wide BOA. It will also have a design and oversight role in which it will establish rules, standards and conventions for systems design and implementation, and will provide technical support to program offices.

With a system designed along the guidelines envisioned, data transmission speed will be increased, data quality will be improved, data access and use will be improved, and the inspection process will become more effective, efficient and productive. A few examples of how the system might be used are included below:

- o Data entry of information on slaughter, processing production, sanitation, animal disease, label approval requests, personnel records, etc. could be performed on-line by field personnel (e.g., IICs). Data quality would be checked interactively by a computer, and productivity gains would be realized by eliminating additional clerical keypunching.

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- o Telecommunications could enhance inspection efficiency by speeding up communications between headquarters and the field. IICs could be alerted to new incidences of animal disease outbreaks and residue problems. These alerts might even be computer-generated using surveillance-type programs which check for geographic or seasonal trends.
- o Laboratory technicians could access product formulations from a label approval information data base to assist in their analysis.
- o Residue sampling could be tied into a laboratory results data base to adjust the intensity of sampling based upon experience.

Estimations of additional personnel, the cost for the procurement of computer equipment, annual maintenance and operating costs, and contractor costs are attached. Additional systems and resource demands placed upon the IRM function by other task forces will be in addition to those listed. The costs included in Attachment A are to upgrade the existing system and information structure to enhance Agency analytical needs, and to put a system into place which can incorporate additional needs which may be forthcoming in the future.

FSIS envisions a five-year start-up time to accomplish these objectives. The first year will be devoted to conducting a long-range agency-wide IRM study with an outside consultant; the study should address implementation strategies pertaining to the task force's proposed approach and provide technical guidance in certain areas such as telecommunications. The next two years will be devoted to instituting organizational and personnel changes required by the new IRM strategies set forth in the IRM study, starting the systems design and analysis for a totally integrated data base environment, and obtaining bids for computer procurement. In the last two years, hardware acquisitions will be made, the new information system will be instituted, and a schedule will be set for the integration of existing data bases into the system.

ATTACHMENT A
ESTIMATED RESOURCE REQUIREMENTS

RECOMMENDATION	ESTIMATED EXPENDITURES	
	ONE-TIME	RECURRING
AREA 1: Increase systems analysts:		
o 49 System analysts ¹	-	\$1,960,000
o Training (\$5,000 each)	\$245,000	-
o Hardware procurement (\$5,000 each)	\$245,000	-
o Hardware maintenance (5%)	-	\$12,250
o Basic Ordering Agreement	-	\$1,000,000
Subtotal.....	\$490,000	\$2,972,250
AREA 2: Increase program analysts:		
o 48 Program analysts ¹	-	\$1,920,000
o Training (\$2,000 each)	\$96,000	-
o Hardware procurement (\$5,000 each)	\$240,000	-
o Hardware maintenance (5%)	-	\$12,000
Subtotal.....	\$336,000	\$1,932,000
AREA 3: Improve quality of information:		
o 5 Systems analysts ¹	-	\$200,000
o Long-range agency-wide IRM study	\$400,000	-
o Hardware procurement for:		
Systems analysts (\$5,000 each)	\$25,000	-
Headquarters/Regional facilities	\$1,450,000	-
o Hardware maintenance for:		
Systems analysts (5%)	-	\$1,250
Headquarters/Regional facilities	-	\$100,000
o Training (\$5,000 each)	\$25,000	-
o Telecommunications usage	-	\$2,000,000
Subtotal.....	\$1,900,000	\$2,301,250
AREA 4: Improve collection of data:		
o 20 Systems analysts ¹	-	\$800,000
o Hardware procurement for:		
Systems analysts (\$5,000 each)	\$100,000	-
2,985 data collectors (\$1,500 each)	\$4,477,500	-
Field laboratories	\$500,000	-
o Hardware maintenance (5%)	-	\$253,875
o Local telecommunications	\$100,000	-
o Training for:		
Systems analysts (\$5,000)	\$100,000	-
2985 data collectors	\$200,000	-
o GSA RFP Contract cost (4% of major hardware acquisitions)	\$203,100	-
Subtotal.....	\$5,680,600	\$1,053,875
TOTAL COSTS:	\$8,406,600	\$8,259,375

¹ Based upon annual salary of \$40,000.

ATTACHMENT B
MEMBERSHIP OF DATA SYSTEMS COMMITTEE

COMMITTEE CHAIR

Paul Taylor, Director
Industrial Engineering and Data
Management Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

SECRETARIAT

Peter Kuhmerker, Operations Research Analyst
Regulations Review and Analyst Unit
Planning Office
Policy and Planning Staff
Food Safety and Inspection Service

Jim Blank, Director
Analysis and Evaluation Office
Review and Evaluation Staff
Food Safety and Inspection Service

Bert Levy, Director
Mathematics and Statistics Division
Science
Food Safety and Inspection Service

Charlotte Miller, Director
Import Analysis Staff
International Programs
Food Safety and Inspection Service

Jerry Skufe, Director
Resource Management and Analysis Staff
Meat and Poultry Inspection Operations
Food Safety and Inspection Service

Donald Tasker, Computer Specialist
Computer Sciences and Telecommunications
Forest Service

Ken Wissmann, Deputy Director
Industrial Engineering and
Data Management Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

CHAPTER VIII

AGENCY TECHNICAL CAPABILITY RECOMMENDATIONS

TECHNICAL CAPABILITY RECOMMENDATIONS

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TECHNICAL CAPABILITY RECOMMENDATIONS

A. STATEMENT OF PROBLEM

In assessing the scientific basis of the Nation's meat and poultry inspection program, the National Academy of Sciences (NAS) has concluded that the Food Safety and Inspection Service (FSIS) has been unable to take full advantage of many of the new technologies available that could be applied to make inspection more effective and efficient. While acknowledging that the Agency is to some degree constrained by its budget and its legislation, the NAS, for the most part, attributes much of the Agency's problem to a shortage of scientific and technical personnel who could develop and implement new inspection technologies.

TECHNICAL CAPABILITY RECOMMENDATIONS

B. NAS RECOMMENDATIONS

The NAS has made several recommendations that may be subsumed under the general heading of Agency Technical Capability:

- o Establishment of a series of standing advisory committees or expert panels.
- o Development of a system of mandatory continuing education and training.
- o Strengthening of interagency liaison with relevant scientific and animal health agencies.
- o Creation of a technically qualified, multidisciplinary inspection team in which no one discipline is dominant.

While each of these recommendations relate directly to the issue of the technical and scientific capabilities of the Agency, they are sufficiently unique as to merit separate consideration.

TECHNICAL CAPABILITY RECOMMENDATIONS

C. FSIS OBJECTIVES AND STRATEGIES IN THE PROBLEM AREA

FSIS believes that in view of its need to utilize innovative technologies to modernize the inspection system, it must introduce fresh currents of scientific thought and objectivity into its policy formulation and program execution. The Agency needs a pool of scientific expertise that could be called upon to critique the way in which inspection is being carried out and to solve old problems in different ways. In deciding which expertise should be Agency staff and which should be utilized in an advisory or contractual capacity, the Agency has used as its guideline the realities of the marketplace (i.e., who can the Agency successfully recruit and keep) and the costs of training.

In accordance with the constraints presented by these factors, FSIS has established a strategic planning goal of recruiting people for certain skills who are already trained in their disciplines. Having identified its requirements for specialized skills, FSIS intends to recruit specialists with skills in food science, food technology, pathology, and public health from the private sector or from other public sector organizations rather than train its own staff in these skills. Training funds will be used to support education for Agency personnel in applied meat and poultry inspection technologies rather than to teach the basic disciplines used in the program. For those specialists that the Agency only uses from time to time or that it is at a comparative disadvantage in recruiting, FSIS will utilize advisory or contractual modes. The more intensive use of scientific and technical expertise in meat and poultry inspection is a crucial factor in the Agency's overall plan to improve the productivity of inspection resources. Therefore, although increased use of high level professional expertise is more expensive, the Agency expects that it can be supported by a more efficient use of its current resources.

TECHNICAL CAPABILITY RECOMMENDATIONS

D. OPTIONS EVALUATION AND FSIS RECOMMENDATIONS

1. STANDING ADVISORY COMMITTEES

NAS RECOMMENDATION

The NAS proposes that FSIS should make greater use of experts, both internal and external, in practically all the disciplines that affect meat and poultry inspection. This would be accomplished through the establishment of one or more scientific advisory bodies composed of representatives from government, industry, universities, and research organizations to facilitate interaction with other USDA agencies, other government agencies, and private groups. Some of the major characteristics of these committees would be:

- o Each would be comprised of a wide array of scientific disciplines including food science and technology, computer applications, microbiology, biostatistics, epidemiology, veterinary medicine, toxicology, systems analysis, animal health, economics, marketing, nutrition, risk analysis, and quality control.
- o They would participate in creating new inspection schemes and review all major Agency policy and regulatory proposals prior to their finalization.
- o They would provide a vehicle for open communications and consultation between FSIS scientists and outside experts.
- o They would provide the basis for peer review and a continuing critique of the inspection program.
- o They would be augmented by periodic public hearings encouraging public participation, and substantial efforts to improve public understanding of the issues and problems of inspection.

OPTIONS

It is the opinion of FSIS that the NAS recommendation has sufficient merit to warrant consideration of all options available to the Agency that address the problem of insufficient outside technical expertise. Four discrete options have been identified which address to some degree the problems outlined by the NAS report.

TECHNICAL CAPABILITY RECOMMENDATIONS

1. Option: National Advisory Committee on Meat and Poultry Inspection

At the present time, FSIS maintains a standing committee as required by the Federal Meat Inspection Act. In particular, the Act advises that "The Secretary may appoint advisory committees consisting of such representatives of appropriate State agencies as the Secretary and the State agencies may designate to consult with him concerning State and Federal programs with respect to meat inspection and other matters within the scope of this chapter, including evaluating State programs for the purposes of this chapter and obtaining better coordination and more uniformity among the State programs and between the Federal and State programs and adequate protection of consumers." This committee, which is known as the National Advisory Committee on Meat and Poultry Inspection, meets twice yearly to provide expert advice and consultation to the Secretary on matters relating to Federal inspection of meat and poultry. This Committee augments the Agency's pool of technical and scientific expertise.

Assessment: This option represents the current Agency program. It is executed by the Executive Secretariat at an annual budget of approximately \$23,000 and requires no changes to any of the Agency's current procedures. However, it is clearly the least effective of the available options for expanding and augmenting the scientific and technical expertise available to FSIS. The committee does not meet often enough nor is the composition suitable for the kinds of technical judgments that it would be asked to make.

2. Option: Expansion of Current Advisory Committee

The existing National Advisory Committee on Meat and Poultry Inspection could be restructured during its biannual charter review to specifically include in its membership more of the types of scientific and technical expertise that are recommended by the NAS report.

Assessment: The present Advisory Committee could be restructured over a period of years as current assignments expire to include more technical and scientific expertise. These changes could be introduced with no additional resource costs to the Agency. However, the advantages that would accrue to this approach would be several years in coming and might not produce, over the long run, a sufficient increase in expertise.

3. Option: Technical Subcommittees

In order to further broaden the scientific and technical base available to the Agency, an additional option would be to utilize the existing National Advisory Committee on Meat and Poultry Inspection as a base while expanding its scope through the creation of a series of specialized technical subcommittees. The subcommittees could be convened on an as needed basis for specific policy and technical questions.

Assessment: Implementation of Option 3 would require additional resources in the form of support staff, travel, and per diem for committee members. Five to ten subcommittees would be convened, comprised of experts in the fields that the NAS report identified such as microbiology, pathology, statistics and the like. The FSIS Executive Secretariat would continue to have responsibility for execution of meetings and meeting-related activities, but with increased staff support from one secretary and two professionals who would handle the requirements for keeping minutes, gathering data, and research report writing. Increased reporting and information management would necessitate procurement of two microcomputers and supporting software. The total costs for this approach are estimated to be between five to ten times the costs associated with operating the current Advisory Committee, based on an estimated ten subcommittee meetings per year. While no new authority would be necessary in order to implement this activity, its effectiveness would still be limited by having scientific subcommittees reporting through a more generalist Advisory Committee. Start-up time for this option would be approximately 1 year to draft charters and make the necessary appointments. Effective output would take an additional year. This option would probably not generate substantial opposition because the subcommittees would be addressing technical issues as opposed to policy issues.

4. Option: Technical Advisory Committees

This option would call for the creation of small standing committees of about five or six experts for each scientific issue or technical discipline of major significance to the Agency such as those mentioned in the NAS report. Each committee would operate independently of any other committee. Responsibility for each committee would rest with the Agency unit with greatest competency, e.g., a Microbiology Committee would report to the Microbiology Division and a Radiobiology Committee would report to the Science program area. However, meetings would not be held without the approval of the Administrator. All of the rules and regulations pertaining to the Federal Advisory Committee Act would apply the operation of the committees.

TECHNICAL CAPABILITY RECOMMENDATIONS

Assessment: This approach has been successful with other agencies, e.g., FDA, and it is generally perceived by outsiders as an effective method of augmenting the agency's scientific expertise, and for opening up the agency's policy-making process for wider public participation. Because the committees would be small in size, it would not be difficult to convene meetings. Moreover, any issue having wider implications could be discussed with more than one technical committee as well as the larger and more diversely composed National Advisory Committee on Meat and Poultry Inspection. This option would not cost any more than forming the technical subcommittees described in Option 3 above, but would provide direct access to each committee.

5. Option: Consultation and Technical Review Network

Another approach to problem would be to create a consultation network comprised of specific subject matter experts that would operate in conjunction with the existing National Advisory Committee on Meat and Poultry Inspection. In order to implement this approach, some changes would be required to the makeup of the current advisory committee so that each technical and scientific discipline mentioned in the NAS report was represented on the committee. Each technical expert serving on the advisory committee would then preside over an established network of specialists in a particular field and would be responsible for presenting to the full advisory committee the views and recommendations resulting from consultations with the network on specific issues and problems. The process might work in the following way: The advisory committee member representing the epidemiological community might seek to develop a consensus on the most effective application of declining FSIS resources in controlling or limiting a specific pathogen. The committee member, with the assistance of FSIS staff, would initiate contact with the network which would consist of designated experts from academic institutions, professional associations, and technical societies. Funds would also be available to convene meetings, hire consultants, and prepare studies. The individual advisory committee member would then submit a summary of findings and recommendations to the full committee which could then deliberate and recommend a course of action to the Agency.

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Assessment: The key to the viability of Option 4 would be in the constitution of the individual networks of consultants available to advisory committee members. It would not be difficult to identify the people and institutions that should be represented. However, it would require a substantial increase in the resources available to the present advisory committee to support meetings of experts, travel, and administrative costs. Existing FSIS staff could be used as executive secretariats to assist in contacting the networks and arranging meetings. Consulting firms might also be hired to set up meetings and prepare responses and recommendations for particular issues. An initial sum of \$2 million would be required in the first year to appoint new advisory committee members, establish the networks, allow for meetings, and provide for the use of consultant's services for each of the following areas: food science and technology, computer sciences, microbiology, biostatistics, epidemiology, veterinary medicine, toxicology, systems analysis, animal health, economics, marketing, nutrition, risk analysis and quality control. When implemented, this would be the most effective of the available options. The only opposition to this measure that might develop would be from any group that felt that it was being excluded from the decision-making process.

FSIS RECOMMENDATION

The primary objective of the NAS recommendation regarding standing advisory committees is the augmentation and expansion of the pool of scientific and technical expertise available to FSIS. FSIS believes that this objective can best be accomplished with least cost and most effect by establishing the technical advisory committees described in Option 4.

2. INTERAGENCY LIAISON

NAS RECOMMENDATION

The NAS report recommends strong liaison between FSIS and other relevant animal health agencies at the Federal, State, and local levels to ensure that no hazards are overlooked.

OPTIONS

FSIS agrees that meat and poultry inspection is a complex undertaking that requires the cooperation and coordination of many State and Federal agencies, each of which share responsibility for making the program work. The inspection and monitoring of animal health is overseen by a vast collection of laws and regulations that have accumulated for more than a

TECHNICAL CAPABILITY RECOMMENDATIONS

century, resulting in a program with splintered and overlapping jurisdictions. Thus, in order to carry out its legal mandates, FSIS must rely on many other organizations for a wide variety of services and support. A few examples are listed below.

- o Food and Drug Administration establishes tolerances for many chemicals residues, food additives, and drugs used in animal husbandry; investigates known or suspected illegal use of drugs on the farm.
- o Department of the Treasury performs customs inspection of incoming meat and poultry products.
- o Environmental Protection Agency sets standards for clean water, sedimentation, chemical and biological hazards, as well as for the potential reuse of water by meat and poultry plants.
- o Department of Defense sets standards and specifications for product destined for military installations and establishes procedures for the utilization of USDA veterinarians in time of disaster.
- o Department of Labor-Occupational Safety and Health Administration sets health and safety standards in meat and poultry plants.
- o Department of Energy establishes standards for energy utilization in plants.

This does not begin to exhaust the complex mosaic of interrelationships that are necessary to carry out inspection. There are cooperative agreements with individual States, independent agreements with foreign countries on regulatory programs, liaison with the European Economic Community, participation in the Codex Alimentarius Commission for the development of international food standards, and more. The NAS recognizes that virtually nothing is done today in inspection that does not rely to some extent on a myriad of other organizations.

The chain of interrelationships that form the inspection process can only be as strong as the weakest links. When any of the organizations in the inspection chain fail to perform their functions adequately, the whole of inspection is reduced in effectiveness. FSIS currently maintains several standing liaison committees and places great emphasis on communication with other governmental bodies. However, it is possible that the good faith efforts of the past will not be sufficient in the coming period of constrained budgets and rapid innovation and change.

TECHNICAL CAPABILITY RECOMMENDATIONS

Four options have been identified for dealing with the problems associated with split or overlapping jurisdictions and the need for effective interagency liaison. The Interagency Regulatory Liaison Group and its activities were reviewed and discussed. However, this type of approach to interagency liaison was not regarded as realistic or viable and was therefore not included as an option.

1. Option: Ad Hoc Liaison Committees

FSIS currently invests heavily in maintaining open communication channels with the many outside organizations that play a part in the inspection process. The Agency's record in this area was not criticized by the NAS report. Therefore, the Agency could be expected to continue to meet its full responsibility under the law by maintaining its current level of liaison with these organizations. However, in the final analysis, this status quo approach to interagency liaison is only as good as the commitment on the part of the outside organizations that must be relied upon for cooperation and assistance.

Assessment: The current Agency approach to interagency liaison, for the most part, consists of ad hoc committee meetings which are periodically convened to exchange information or discuss a particular problem. Resource requirements for these meetings are relatively small. The primary limitation to the effectiveness of this option is in acquiring the right kinds of expertise for the problem at hand. In some cases it is not possible to get subject matter experts to serve on these committees and at other times those who are available cannot speak with authority for their organizations.

2. Option: Interagency Liaison Conference

This option proposes to continue FSIS' current interagency liaison activities while adding a procedure that would improve the opportunity for dialogue. Either once a year or once every two years, FSIS would sponsor a conference of the major organizations that have roles to play in meat and poultry inspection. The conference might be hosted by an organization such as the National Academy of Sciences.

TECHNICAL CAPABILITY RECOMMENDATIONS

Its purpose would be to promote a dialogue on the best ways of improving communications among the affected organizations and how the problems cited in the NAS report might be most effectively ameliorated. This would be a relatively inexpensive way to periodically tackle the problems brought on by split jurisdictions, conflicting and overlapping laws, regulations, and mandates and divergent political and institutional priorities.

Assessment: The Administrator and his appropriate deputies would have the responsibility for convening a conference for the promotion of interagency liaison. The Executive Secretariat would produce the necessary conference reports and records which might require limited IRM support in gathering and disseminating information. Given the number of organizations that play a role in meat and poultry inspection, it is estimated that up to 300 people would be in attendance. If FSIS were to finance the entire affair, the cost would be approximately \$300,000. Relying on other organizations to fund their own per diem and travel costs would greatly reduce the costs to FSIS; however, there would be no assurance of adequate attendance and representation. Such a conference could be very effective in addressing the problems of inter-organizational communications, and might be expected to produce an agenda in this area for years to come. If planning were to begin this year, a conference could be held by January of 1987. Support for a conference of this type would probably be great and opponents few as long as all interested parties were invited to participate.

3. Option: Unified Jurisdiction

Another approach to the problem would be to seek to remove the need for interagency liaison by seeking to unify jurisdictions and thus eliminate the duplication of effort that is inherent in the current structure. Under this approach FSIS would assume the lead role in finding ways -- perhaps by convening a conference such as the one described in the preceding option -- to bring within its jurisdiction all of the laws and regulations necessary to assure the availability of healthy, drug free animals from the farm to the consumer. This is an idea that has been proposed before, but has never been able to survive the interests and motives of the affected organizations. However, during the next four years of deficit reduction activity, many organizations may find it in their own self interest to discover less costly ways of carrying out their sometimes duplicative legal mandates. The environment may finally be right for streamlining and consolidating inspection services.

TECHNICAL CAPABILITY RECOMMENDATIONS

Assessment: The responsibility for implementing this option rests with the Executive and Legislative branches of the Federal Government and the affected Cabinet Officers. There is no way to realistically estimate the impacts that implementation of this option would produce. It can be anticipated that the disruptions in the near-term would be sizeable, but that the long-term benefits would also be sizeable. It can also be anticipated that there would be major opposition to this approach from practically every quarter. The primary opponent would very likely be the regulated industry itself, which would be concerned about potential uncertainty and disruptions to inspection.

4. Option: Computer Teleconferencing Network

FSIS could also assume a lead role in improving interagency liaison by establishing a computer teleconferencing network. The conference of public health agencies described in option 2 above, might be used as a vehicle for discussing the specifics and gaining the consensus necessary to establish such a network. The network itself would require the linking of some of the individual agencies' mini- and micro-computers by telephone modems through a central "translator" mainframe. The equipment could be purchased through contributions from the participating agencies or rented on a time-share basis. The "translator" mainframe would enable the many different computers used throughout the Government to communicate directly with one another. This arrangement would enable designated offices within each organization -- such as Science in FSIS -- to come on line simultaneously when deliberation on a particular problem is necessary, or simply to routinely pass information within the network. The goal of such a network would be to place every organization that plays a part in meat and poultry inspection on line, enabling each to instantaneously post and display information on an as needed basis. For example, an FSIS office experiencing a problem with an Occupational Safety and Health Administration requirement for non slip surfaces in plants could open a network dialogue on the unsanitary nature of such porous surfaces. The teleconferencing capability would enable a problem statement to be entered and stored in the network until other organizations on the network could check their electronic "in boxes" and make a response. The dialogue could then continue as long as necessary until some resolution was found to the problem. With the expense of a particular teleconferencing system spread among several agencies, the costs of this option would be small when compared to the benefits.

TECHNICAL CAPABILITY RECOMMENDATIONS

Assessment: The Administrator and the appropriate Deputy Administrators would have the responsibility for carrying out Option 4. The execution of tasks associated with setting up a computerized teleconferencing network would be handled by each FSIS program area and outside agencies participating in the network. This approach assumes the use of on-hand equipment, personnel, and services with the exception of the interface equipment such as telephone modems and the interface "translator" computer. The cost of this service on a time-share basis would probably not exceed \$15,000 a year. The cost would be evenly distributed among all of the participants in the system making the FSIS share of the costs very small. It should be noted that significantly larger costs might accrue if attempts were made to directly link other agencies' data systems. The effectiveness of this approach would depend largely on the preparation that went into setting up the network. For instance, some type of preliminary meeting of the prospective users of the system would be desirable in laying out the goals and procedures. A conference such as the one described in Option 2 above would be the most effective means of initiating the system. With a preliminary meeting, the system could be in place by January of 1987. No major opposition to this approach is anticipated.

FSIS RECOMMENDATION

The best solution to the problem of improving interagency liaison is through the implementation of a program that combines the elements of Options 2 and 4. FSIS should cohost with the National Academy of Sciences, a conference on interagency liaison that involves every single organization that now plays a role in meat and poultry inspection. As a part of that conference (possibly a workshop or major agenda item), the teleconferencing network system would be proposed and discussed. FSIS would assume the lead role in setting up the conference and promoting the networking system. The cost to FSIS in the second quarter of FY 1987 would be approximately \$300,000.

3. TECHNICALLY QUALIFIED INSPECTION TEAM

NAS RECOMMENDATION

The assumption underlying each recommendation in the NAS report that pertains to the Agency's technical capability is that the use of more technically trained personnel will yield a more effective inspection program. Following this line of reasoning, the report recommends that there be:

TECHNICAL CAPABILITY RECOMMENDATIONS

Adequate technical support for inspection operations from a team of qualified personnel, including substantial emphasis on veterinary medicine, food science, public health, food engineering, food technology, epidemiology, pathology, toxicology, microbiology, animal science, risk analysis, systems analysis, statistics, computer science, and economics. Similarly, managers should have expertise in several relevant disciplines, including veterinary medicine, food science and technology, nutrition, public health management; no one discipline should dominate. [pp. 151-152].

Stated more succinctly, the NAS appears to prescribe the infusion at all levels of FSIS of technically trained personnel representing in equal proportion all of the scientific and technical disciplines. This multidisciplinary cadre could then be expected to produce an eclectic approach that would employ the latest developments in science and technology in solving the problems of inspection.

OPTIONS

FSIS concurs with the assumption that more technically trained personnel interspersed throughout the inspection program would produce a more effective and productive program. In acting on this assumption, the Agency has taken several steps in recent years to broaden its pool of specially trained personnel. This is particularly evident in the current FSIS training curriculum and in the recent decision to begin hiring food technologists to fill processing inspection posts.

Six options exist which, if implemented, would increase the numbers and the quality of technical specialists available to the inspection program.

1. Option: Improvement of the Present Program

This option represents the continuation of the current FSIS program of upgrading the existing inspection workforce through education and training and the recruiting of more technically trained specialists to fill inspector vacancies as they arise. This approach is founded on the belief that the current inspection workforce contains a wealth of valuable experience and skill that may be cost effectively enhanced. Toward this end, FSIS has created an extensive curriculum of inspection-related course work that may be pursued through home study, short-term study assignments, and in formal classes. Many of the courses presently being offered are specifically designed to develop or augment the

TECHNICAL CAPABILITY RECOMMENDATIONS

types of skills that have been enumerated in the the NAS report such as:

- o Public Health and Preventive Medicine
- o Epidemiology
- o The Sciences
- o Food Animal Production
- o Management Science
- o Quality Systems
- o Food Science and Technology
- o Computer Sciences

A combination of specialized training and the commitment to hire food technologists to fill all new processing inspection vacancies constitutes the current program. This, and the ongoing efforts to attract the most highly skilled technical personnel in all fields, characterize the way in which FSIS is presently attempting to increase its technical capability.

Assessment: Option 1 represents a continuation of the current FSIS program which is described above. It is carried out within the current budget and legislative authority and enjoys widespread support both inside and outside of the Agency.

2. Option: Establishing a Protected Training Budget

A second option exists which consists of enhancing Option 1 above through the institutionalization of the status quo. This would mean devising a method through which the current FSIS program would be protected from future political and budgetary constraints. This could be accomplished by determining a formula for the minimum percentage of total annual budget that should be allocated to the training and recruitment of personnel and making this portion of the budget off limits to cuts and reallocations.

Assessment: Option 2 -- the protection of current levels of training and recruitment funds from cuts or reallocation could be carried out at the discretion of the Administrator. In all other respects it would be a continuation of the current program.

3. Option: Immediate Recruitment of Needed Expertise

A third option would be to conduct an Agency-wide audit of the types and numbers of technical specialists needed (as outlined in the NAS report) to support the Agency's strategic goals for public health effectiveness and productivity. A request would then be submitted in the FY 1988 budget for funds to begin immediate hiring and recruitment actions in that fiscal year.

Assessment: In order to implement Option 3, each Deputy Administrator would be required to identify their specific needs with respect to scientific and technical personnel. The current Agency goal of hiring 1,000 food technologists would be a starting point for estimating the costs associated with an accelerated recruitment program. The personnel costs (fully loaded) for 1,000 staff would be \$33 million. If the recruitment actions were spread over three years, attrition rates would obviate the need to implement early retirements or reductions-in-force to create vacancies. These activities would greatly increase the cost of an accelerated recruitment program. The optimum approach would be to budget for \$11 million a year beginning in FY 1988 and continuing through the end of FY 1990. This would enable the Agency to assess its hiring goals and make necessary adjustments and reassignments of personnel. This approach would be extremely effective in addressing the Agency's requirements for technical and scientific personnel. It would not require any new legislative authority and it would not be in conflict with the standing FSIS policy to handle recruitments in a cost-effective, evolutionary manner. However, this approach would likely be opposed on all fronts, from the employee unions fearing for jobs, to the Congress resisting increased costs, to the industry fearing uncertain changes in inspection coverage.

4. Option: Occupational Specialty Structure

A fourth option available to the Agency, would be to create an "Occupational Specialty Structure" that could be used to recruit, retain, and promote specialists. In effect this would require the establishment of a separate career and promotion ladder for certain hard to retain professional skills. Such a system would allow professionals in critical skill areas to practice their specialty throughout the course of their careers and to progress in salary and benefits based on performance rather than through the assumption of duties such as management and supervision. In addition, other inducements for joining and remaining with FSIS might be made available, such as bonuses based on tenure, assistance in pursuing advanced degrees, sabbaticals, and awards for inventions and discoveries.

TECHNICAL CAPABILITY RECOMMENDATIONS

Assessment: The creation of a "Occupational Specialty Structure" would require Department-level approval and coordination with the Office of Personnel Management. Once approved, the program could be executed under the direction of the Administrator. Depending on the quantity and mix of the incentives that could be utilized, there would be additional costs associated with establishing a specialized recruiting and retention structure. These costs cannot be quantified until the number of experts and type of expertise to be included in the program is identified. One way of beginning such a program would be to establish a recruitment objective of 50 scientists and technicians for FY 1988 and budget an additional \$10,000 per person as a recruitment incentive. This would be a total program cost, including salaries and incentive, of approximately \$2 million for the first year.

After the first year, accurate estimates for future recruitments could be prepared based on experience. This approach would be very effective in recruiting and retaining the kinds of skills that FSIS will require in the future in order to implement an inspection program that is more scientifically and technologically based. Likely opponents of such a program would be the Congress for reasons of cost and the industry for reasons having to do with uncertainty and disruptions to inspection.

5. Option: Train and Upgrade the Current Workforce

Still another option available to the Agency would be to identify the professional skills and specialties that are needed now and will be needed in the coming years to implement the NAS recommendations, and to train as required to meet those needs. This approach is different from the Agency's present program in that it would be on a much larger scale. It would seek to draw from within the FSIS inspector ranks for candidates for special training and advanced scientific degrees and skills. Specialized curricula requirements could be handled in the schools and universities in much the same way they are currently being handled for food technologists. In adopting this approach, FSIS would be called upon to institute a large training program for its current workforce that could be expected to produce a uniquely qualified cadre of experienced and well-trained inspectors and supervisors.

Assessment: This option assumes that FSIS would train one half of the 1,000 food technologists required for inspection modernization and recruit the other half. The trainees would be drawn from the ranks of the current workforce and

TECHNICAL CAPABILITY RECOMMENDATIONS

replaced by temporary employees while they were at school on a full-time basis. The cost of full-time replacement and training of 100 employees per year would be \$8 million per year. Utilizing this approach, FSIS could continue to recruit food technologists at the current rate and reach its recruitment objective of 1,000 in 5 years instead of the current projection of 10 years. The employee union might be expected to oppose this measure for the same reason it opposes the current program. Congress would also be hard to persuade in a time of constrained budgets.

6. Option: Basic Ordering Agreement for Expertise

The last option for augmenting the technical skill levels in the Agency would be to continue to increase in house expertise at the current rate and to establish a contract, at the Agency level, for a Basic Ordering Agreement to provide consultants to programs on an as needed basis. In this instance, it would be necessary to identify a prime contractor who could supply, or subcontract to supply, subject matter experts for studies, methods development work, review of Agency proposals, and expert opinion and advice. This approach would provide the ability to fill in any gaps in Agency expertise that exist for a period long enough to allow for other alternatives and ongoing programs to mature.

Assessment: This option would be executed just like an ordinary contract for outside services. However, the services rendered would be guidance for solving scientific and technical problems associated with inspection modernization. One example might be contracting for applied research on computer-assisted visual inspection systems. The goal of such activities would be the rapid adoption of new technology-based systems of inspection. A first year set-aside of \$2 million dollars (FY 1988) could be used to test the efficacy of this approach by purchasing the equivalent of 100 staff years of specialized technical expertise. More money could be set aside in the out years if the program proved advantageous. This approach would be effective in augmenting the Agency's technical capability on a small scale. It would probably not generate adamant support or opposition among FSIS' constituent groups.

TECHNICAL CAPABILITY RECOMMENDATIONS

FSIS RECOMMENDATION

FSIS believes that each of the six options discussed above has merit. Portions of each option could be combined into one program that protects the current training and recruitment activities while moving swiftly to fill the Agency's needs for other types of scientists and technicians. If the Agency were called upon to select a single option, the recommended order of priority is as follows: Options 1, 2, 3, 5, 6, and 4. Although the creation of an "Occupational Specialty Structure" (see Option 4) ranks last on the FSIS priority list, it is still felt to be an important part of an overall program of recruitment and retention.

4. EDUCATION AND TRAINING

NAS RECOMMENDATION

Recruiting and developing a more highly educated and technically skilled workforce is one important part of increasing the Agency's overall technical capability. Another important part is upgrading the existing workforce and maintaining a minimum level of competence in each member of the inspection staff, irrespective of where they fit in the total inspection picture. The NAS report recommends that address education and training imply that FSIS does not have a workforce that is sufficiently educated or trained to accommodate needed technical and scientific changes to inspection. In order to remedy this situation the NAS observes that there is "a need for adequacy of resources, knowledge, and further promotion of initial and continuing education. A mandatory system of initial and continuing education for inspection personnel...should also ensure that all personnel be recertified on a continuing basis to ensure continued competence."

OPTIONS

The NAS report has identified an area for improvement that has already been singled out by the Agency for special attention. FSIS currently conducts many different types of initial and continuing education either at its own training facility or in conjunction with private sector educational institutions. The primary constraint that limits how fast and how far FSIS can move in this area is budget. Nevertheless, FSIS concurs with the observation that more can and should be done to raise the technical competency of the staff and to ensure minimum levels of on the job performance through some form of testing and recertification.

TECHNICAL CAPABILITY RECOMMENDATIONS

Five options are listed below which could be used individually or in combination to produce a higher level of technical competency in the Agency's staff. These options assume that FSIS will, at the very least, continue to carry out its current commitment to hire 1,000 food technologists in the next ten years and set up a program to qualify many of its present processing inspectors as food technologists.

1. Option: Improvement of Current FSIS Training Program

In adopting this option, the Agency would build on its present extensive program of continuing education and targeted recruitment of food technologists. However, the following additional activities would also be implemented in order to enhance the present program:

- o Examine and evaluate all training classes and activities to determine the precise program and management goals to be achieved by the instruction.
- o Define the particular needs of each program area through the involvement of senior managers and develop a training curriculum that serves the needs of the whole Agency and addresses the Agency's management goals.
- o Establish tight, coherent, and measurable learning objectives that are tied to Agency management goals that can be demonstrated and accurately measured through pretesting and post-testing.
- o Validate the accomplishment of training objectives through testing, and tie individual achievement to performance evaluations and Individual Development Plans.
- o Evaluate the placement of the current training program within the Agency's organizational structure to ensure that it is optimally placed.
- o Emphasize the importance of the role that initial and continuing education play in meeting the organization's goals through a high level management commitment and continued promotion of the Agency's training activities.
- o Certify that all new-hire employees are fully qualified to perform their inspection duties upon completion of all required training and education and prior to the end of the probationary period.

TECHNICAL CAPABILITY RECOMMENDATIONS

Assessment: Option 1 represents the Agency's current program with some modifications. Current procedures are being studied by an internal task force headed by the Agency's Associate Administrator. The results of this study will determine the configuration of education and training activities under current and projected budget levels.

2. Option: Accelerated Recruitment and Replacement

This option would also build on the Agency's present activities. However, it would greatly accelerate the process by relying less on evolution and attrition and more on rapid recruitment and replacement. Under this scenario, FSIS would identify its total requirements for new technical personnel such as food technologists, pathologists, epidemiologists, and public health professionals and begin to implement a program of accelerated recruitment to fill vacancies and replace unskilled employees.

Assessment: In order to implement Option 2, each Deputy Administrator would be required to identify their specific needs with respect to scientific and technical personnel. The current Agency goal of hiring 1,000 food technologists would be a starting point for estimating the costs associated with an accelerated recruitment program. The personnel costs (fully loaded) for 1,000 staff would be approximately \$30 million. If the recruitment actions were spread over three years, attrition rates would obviate the need to implement early retirements or reductions-in-force to create vacancies. These activities would greatly increase the cost of an accelerated recruitment program. The optimum approach would be to budget for \$10 million a year beginning in FY 1988 and continuing through the end of FY 1990. This would enable the Agency to assess its hiring goals and make necessary adjustments and reassignments of personnel. This approach would be extremely effective in addressing the Agency's requirements for technical and scientific personnel. It would not require any new legislative authority and it would not be in conflict with the standing FSIS policy to handle recruitments in a cost-effective, gradual manner. However, this approach would likely be opposed on all fronts, from the employee unions fearing for jobs, to the Congress resisting increased costs, to the industry fearing uncertainty and change.

3. Option: Employee Interchange Program

This option also would build on the progress and plans that are now underway. The Agency would continue to implement the present program of recruiting specialists as vacancies arise and upgrading the skills of the present workforce.

However, it would also endeavor to establish a comprehensive program for the exchange of personnel between FSIS and academe through interactive liaison and cooperative agreements with professional schools, universities, professional associations, and scientific groups. This would be expected to promote the cross training of personnel, the exchange of ideas, and a sensitivity in the scientific community to the role and importance of meat and poultry inspection. In addition, FSIS would actively promote the self improvement of its technical and scientific staff through further education, pursuit of advanced degrees, board certification, and other forms of professional achievement.

Assessment: Option 3 could be implemented under current Agency policy and legislative authority. It represents a relatively low cost approach to expanding education and training at FSIS. Beginning in FY87, the Agency could select several people for the exchange program.

In cases where a one on one exchange with an outside organization could be effected, there would no direct costs associated with the program. In cases where there were no replacements for FSIS employees, the cost would be approximately \$45,000 per person which would include all direct training costs, salary, tuition, per diem and travel. The program could be carried on indefinitely or as long as necessary to achieve a satisfactory level of comparability between FSIS and private sector technical and scientific experts. This program would be highly effective for its cost in providing new insights and skills to the Agency as well as academe. It would receive no major opposition or support from FSIS constituent groups.

4. Option: Recertification Program

This option could be implemented alone or in combination with any of the other options. Its main objective would be continued evaluation and recertification of the workforce. It would require the development of means to measure the skill level of employees in all Agency job series and a demonstration of minimum levels of competency in carrying out those skills. Employees failing to demonstrate adequate competency would be required to prepare a suitable program of additional training and education and to submit an Individual Development Plan for accomplishing that training. Continued progress would be reflected in the employee's annual performance evaluation.

TECHNICAL CAPABILITY RECOMMENDATIONS

Assessment: This option could be carried out at the discretion of the Administrator with no required changes to current authority. It would be executed in conjunction with the appropriate Deputy Administrators who would be required to audit the job series of their employees and provide a listing of the skills that would be recertified under this program. A committee representing each of the program areas would establish uniform Agency-wide recertification standards for each job series involved in the inspection program. Existing computer equipment could be used to build an inventory of skills matched to names of employees and the expiration dates of their current certificates. Actual recertification of a program area's personnel would be carried out by the program area. This type of recertification would be very effective in establishing and maintaining minimum acceptable levels of competence in jobs directly associated with inspection. It could be started as early as the beginning of the 1987 fiscal year and could be expected to produce meaningful results by the following year. Recertification in this or any other form would be opposed by employee unions who might also enlist some members of Congress in also opposing the measure. Industry and consumer groups would likely support any procedure that would produce a more standardized and uniform delivery of inspection services.

5. Option: Office of Standardization and Evaluation

This option would strive to accomplish the same objectives as the preceding option. The chief difference would be in execution. It too would require an inventory of the specific skills required for each job series that FSIS utilizes and development of tests that could effectively and accurately measure the performance level of those skills. However, the administration of testing and evaluation would be carried out by an independent Office of Standardization and Evaluation which would report directly to the Administrator. Standards for evaluation would be developed through the participation of the appropriate program areas within the Agency. The Office would conduct regularly scheduled and unscheduled evaluations of personnel in the field for the purpose of assessing professional competency in their job series. Passing grades would be required for annual recertification. Failures would be tested again after receiving remedial training. Continued failures might be reassigned to non-critical duties. Particular emphasis would be placed on testing of personnel in critical areas of operation such as plants operating under Total Quality Control or other forms of critical control point monitoring.

TECHNICAL CAPABILITY RECOMMENDATIONS

Assessment: The purpose of this option would be to achieve considerably higher standards of on-the-job competence and uniformity than the approach described in Option 4. To accomplish this it would be necessary to establish and staff an Office of Standardization and Evaluation initially staffed with three professional evaluators and one clerical support person. Planning for such an office could be carried out by FY 1987. A budget of \$175,000 would be required in FY 1988 that would support staff, IRM requirements, travel, per diem, and overhead. The office could be fully operational by the end of FY 1988 however, it would probably take three to five years before the operation became highly effective in ensuring that inspection personnel were fully competent and appropriately certified to perform their inspection duties. Employee unions would oppose this measure as would their representatives in Congress. The industry might also oppose an activity that would appear to be a new form of review and evaluation. Consumers could be expected to endorse this approach.

FSIS RECOMMENDATION

FSIS recommends the adoption of Options 1, 3, and 4 as a comprehensive approach in improving the Agency's overall education and training program. The existing program should be improved along the lines outlined in Option 1, recertification should be instituted as described in Option 4, and an exchange program between FSIS and academe put in place to round out the Agency's efforts to stay abreast of the latest changes in science and technology.

ATTACHMENT A
MEMBERSHIP OF AGENCY TECHNICAL CAPABILITY COMMITTEE

COMMITTEE CHAIR

Bill Dennis, Director
Processed Products Inspection Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

SECRETARIAT

Charles Danner, Director
Planning and Coordination Unit
Planning Office
Policy and Planning Staff
Food Safety and Inspection Service

Tom Crider, Staff Officer
Quality Control and Inspection Procedures
Evaluation Branch
Processed Products Inspection Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

April Fisher, Program Analyst
Analysis and Evaluation Office
Review and Evaluation Staff
Food Safety and Inspection Service

Ron Gurley, Chief
Employee Development Branch
Personnel Division
Food Safety and Inspection Service

Charles Harmon, Executive Assistant
Regional Operations
Meat and Poultry Inspection Operations
Food Safety and Inspection Service

Bert Levy, Director
Mathematics and Statistics Division
Science
Food Safety and Inspection Service

Jim Payne, Assistant to the Deputy
Administrator
Meat and Poultry Inspection Operations
Food Safety and Inspection Service

CHAPTER IX

PUBLIC EDUCATION RECOMMENDATIONS

PUBLIC EDUCATION RECOMMENDATIONS

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PUBLIC EDUCATION RECOMMENDATIONS

A. STATEMENT OF PROBLEM

The mission of the Food Safety and Inspection Service is to assure food is safe, wholesome, and truthfully labeled, as required by the Federal meat and poultry inspection laws. USDA inspectors make sure products are safe when they go into commerce. It is up to consumers to make sure the inspection process is completed -- by handling meat and poultry properly. In this effort, educational campaigns are important, and FSIS has conducted an intensive food safety campaign since 1972.

The present food safety campaign was brought on by two specific events: first, the publication of a major study on salmonellosis by the National Academy of Sciences in 1969; and second, a 1972 suit against USDA by the New Jersey Director of Consumer Health Services, the American Public Health Association and several other health-related groups. The NAS study found that the vast majority of salmonellosis incidents were directly attributable to faulty food-handling practices in home and food service establishments. A massive educational effort was recommended. The study estimated it would cost several hundred million dollars a year to control salmonella in meat plant, and because of the widespread and naturally occurring nature of the organism, no guarantee could be made the program would be effective. The 1972 suit asked USDA to require meat and poultry labels to contain a warning that meat and poultry might contain food poisoning organisms and also to provide information on proper food handling. USDA's defense was that it was more effective to conduct a nationwide consumer education campaign than to restructure the labeling system. The judge found USDA's rationale to be appropriate and reasonable and ruled in the department favor.

USDA established the U.S. Advisory Committee on Salmonella in 1975 to recommend ways of reducing the incidence of salmonellosis. Among the group's seven key recommendations was "emphasis on educational programs for consumers and food handlers on the importance of food safety and decreasing salmonella contamination in the food supply.

At present, FSIS has a comprehensive education and information program largely directed to a general audience. It includes publications, a periodical magazine, the children's food safety poster contest, the Meat and Poultry Hotline, television public service announcements, outreach with non-governmental organizations, and preparation of other material directed to information multipliers, such as feature stories.

B. NAS RECOMMENDATIONS

The six NAS recommendations addressed here are:

- o Educate the general public, health care personnel, educators and Extension Service workers on the safe handling of meat and poultry.
- o Procedures on safe handling and processing of meat and poultry in the kitchen are well established and should be reemphasized to the public through appropriate educational vehicles.
- o Expand the information program and continue preparing packets of information (e.g., literature, films, and slides) for teachers and educational institutions, health care providers, extension services, and the general public.
- o Encourage individual consumer responsibility for food safety through effective education programs aimed at the general public beginning with school-aged population.
- o From a disease control standpoint, labels, stickers or inserted leaflets should be used to provide useful information, when appropriate, on safe ways to thaw, cook and handle (e.g., cool and reheat) cooked products and should list precautions to avoid cross-contamination.
- o Encourage public participation in the development and operation of the national residue program and make substantial efforts to improve public understanding.

The Agency noted that the recommendations were very general and broad and, for the most part, did not call for specific actions. As a result, FSIS decided to address the identified problems by outlining some general recommendations for an effective public education program. In doing this, the group considered the comprehensive education program now being carried out by FSIS.

PUBLIC EDUCATION RECOMMENDATIONS

C. FSIS OBJECTIVES AND STRATEGIES IN THE PROBLEM AREA

FSIS agrees with the NAS Committee that public education is necessary to ensure that meat and poultry are handled properly after they leave the jurisdiction of the inspector. The Agency's strategic policy goal of assuring public confidence in the meat and poultry supply is a broad commitment to the consumer do everything necessary to ensure the delivery of a clean, wholesome, and unadulterated product all the way to the point of consumption.

FSIS has identified the following problems which require public education;

- o Meat and poultry products are responsible for a majority of food borne illnesses;
- o Enteric pathogens are a major health problem;
- o Young children and the elderly are at high risk;
- o Bacterial contamination can occur in the food chain and in institutional food preparation areas;
- o The industry is reluctant to do consumer food safety education; and
- o Food safety education efforts are largely piecemeal and uncoordinated.

D. OPTIONS EVALUATION AND FSIS RECOMMENDATIONS

FSIS grouped the NAS recommendations into three general categories for the purpose of making recommendations: consumer food safety education, industry involvement, and residue program. These were matched with the problem areas identified by the Committee (Attachment A).

1. Consumer Food Safety Education

NAS RECOMMENDATION

Educate the general public, health care personnel, educators and Extension Service workers on the safe handling of meat and poultry.

Procedures on safe handling and processing of meat and poultry in the kitchen are well established and should be reemphasized to the public through appropriate educational vehicles.

Encourage individual consumer responsibility for food safety through effective education programs aimed at the general public beginning with school-aged population.

Expand the information program and continue preparing packets of information (e.g., literature, films, and slides) for teachers and educational institutions, health care providers, extension services, and the general public.

PROBLEMS ADDRESSED

- o Meat and poultry, for which FSIS has the major regulatory responsibility, were implicated in over half of the food-borne disease outbreaks reported to the CDC from 1968-1977.
- o Enteric pathogens are a major health problems and an economic burden.
- o At high risk from food-borne microbial infections are young children and the elderly, although healthy adults may also suffer serious illness and long-term effects.
- o The major contributing factors to outbreaks of food-borne illness in food service establishments are basic mishandling and cross-contamination practices known to FSIS and contained in its current information materials.
- o Federal, State and local government education efforts are piecemeal and largely uncoordinated.

PUBLIC EDUCATION RECOMMENDATIONS

FSIS agrees that the current food safety education program should be supplemented in response to the continuing increase in food-borne illness incidence and severity.

OPTIONS

1. Option: Continue the food safety education program in its present structure and approach.

Currently, FSIS distributes food safety publications to a wide range of audiences. In fiscal year 1985, over 1.1 million food safety publications were distributed. The foundation of the education program are two general audience publications: The Safe Food Book and Talking About Turkey. FSIS supplemented this with the Children's poster contest (for kindergarten through 6th grade school children) which attracted 40,000 entries; a National Consumer Week project involving distribution of a teaching kit for junior high economics students in the Nation's 9,600 largest schools; publication of Food News for Consumers, a periodical designed for information multipliers and mailed to 1,500 food editors, Extension agents, and nearly 2,000 paid subscribers; operation of a toll-free Meat and Poultry Hotline which receives 2,000 calls a month; and outreach with non-government organizations, national magazines and other news media to promote food safety information.

The cost of this program is approximately \$1 million annually. The program is largely the responsibility of the Information and Legislative Affairs Division with input from the FSIS program staff and outside experts. In recent years, ILA has solicited support from the industry for such projects as the children's poster contest and "Talking about Turkey." For the most part, however, the education program is funded by the Agency.

Without doing a comprehensive evaluation of the program, it would be difficult to assess its overall effectiveness.

2. Option: Develop a strategy for targeting messages and, using existing resources, develop appropriate messages and vehicles to reach the targeted audiences. This would include an assessment of the potential target groups, an assessment of the groups most neglected by present education efforts -- within and without FSIS -- and an assessment of the information needed by the targeted groups.

In broadening the existing education program, it would be necessary to identify target groups and the vehicles for reaching them. As an example, a chart (Attachment B) of potential targets was compiled, but lacked sufficient

information to allow for a priority ranking of the groups. Such a ranking should be done by the Information and Legislative Affairs Staff based on a number of factors outlined in the criteria for designing an education program (Attachment C): which groups have the highest incidence, which groups are not now reached by a food safety education program, and which groups have the highest potential for being reached cost-effectively.

FSIS should also assess the current education efforts underway in the Federal, State and local governments as well as by the industry. This will aid in determining which of the target groups are not now receiving information.

Finally, FSIS needs to know the level of knowledge and attitudes toward food safety among the affected target groups or the information multipliers we would use to reach the target groups. To accomplish these points FSIS should:

- o Develop a comprehensive list of target groups, the appropriate vehicles for reaching them, and an assessment of their need for food safety information. ILA should take the lead in this, calling on experts in education, epidemiology, and other areas relevant to the potential target groups. A priority ranking of the groups should be developed by ILA taking into consideration the Agency's strategic goals and public education criteria.
- o FSIS should take the lead in initiating a coordinating committee for food safety education efforts by Federal, State and local governments and the private sector. This could be patterned after the Sodium Education Task Force, which FSIS participated in and which served as an information clearinghouse on government information activities on sodium. Such a group helps avoid duplication by providing an forum for exchanging information and could possibly result in joint information programs.
- o Once a target group is identified, FSIS should survey the level of knowledge and attitudes toward food safety within the groups before preparing an education campaign. This would aid in designing messages which address the specific needs of the targeted group and are, therefore, more effective in changing behavior.

The activities in this option would be done within the existing resources of FSIS. ILA would be the responsible staff, with assistance from the program staff for technical information and from the Policy and Planning Staff in conducting surveys of consumer knowledge and attitudes.

PUBLIC EDUCATION RECOMMENDATIONS

Implementation of the recommendations may have to be spread over several years because of budget constraints. However, by developing a priority list, FSIS can be assured of dealing with the most critical and most solvable problem areas first.

Based on existing knowledge in the design of education programs, a targeted approach would be more effective than a general education approach.

3. Option: Improve and expand the current general information program by (1) making a formal evaluation of its effectiveness and (2) developing a strategy for targeting new messages and materials to specific audiences.

As with Option 2, this would include an assessment of the potential target groups, an assessment of the groups most neglected by present education efforts -- within and without FSIS -- and an assessment of the information needed by the targeted groups. Using this information the Agency would develop new materials such as audiovisuals, posters, non-English material, etc. to meet the needs of specific target audiences and the information vehicles that reach those audiences.

This option recognizes the value of the general public information program that now exists, and it would improve that program by evaluating its effectiveness and making changes accordingly.

At the same time, under this option, the Agency would take advantage of the benefits of targeting messages and materials to specific audiences (see option 2).

To undertake this option, the Agency would need to commit an increased level of funding or secure cooperative funding from the private sector or other government agencies. Furthermore, FSIS would have to commit the resources of ILA and the Policy and Planning Staff to design and conduct the evaluation and the assessment of the information needs of the target groups.

FSIS RECOMMENDATION

The Agency recommends Option 2. This option would continue the present education program for the general public on a perhaps more limited scale while also incorporating a program of targeted messages for specific audiences to improve overall effectiveness of the education program. Furthermore, the NAS recommendation suggested a number of groups that should receive

attention from FSIS in its education program -- health care personnel and educators. The targeted approach would make communications which those groups more effective.

FSIS specifically recommends an education campaign for the general category of institutional food preparers, which were frequently listed (Attachment B) as being relevant to food poisoning problems in several target groups.

2. Industry Involvement

NAS RECOMMENDATION

From a disease control standpoint, labels, stickers or inserted leaflets should be used to provide useful information, when appropriate, on safe ways to thaw, cook and handle (e.g., cool and reheat) cooked products and should list precautions to avoid cross-contamination.

PROBLEMS ADDRESSED

- o The majority of industry is reluctant to do consumer food safety education.

FSIS agrees with the concept of encouraging processors to include food safety information with fresh meat and poultry products. This would be in keeping with the Agency's stated goal of encouraging industry responsibility for the safety of its products. Furthermore, it would be in line with good educational theory in that consumers would receive information about food safety at the time they would need it.

OPTIONS

1. Option: Publish a regulation requiring food safety information as a part of the labeling on fresh meat and poultry.
2. Option: Work with one segment of the industry -- turkey processors, for example -- to encourage them to include thawing and cooking information on their packaging. If successful, this effort could be expanded to other fresh meat and poultry products.
3. Option: Provide incentives to processors to take steps to reduce bacterial loads on their products.

PUBLIC EDUCATION RECOMMENDATIONS

FSIS RECOMMENDATION

The Agency recommends a combination of Options 2 and 3, noting that the Agency has already underway a proposed program to provide incentives to processors who voluntarily take steps to lower salmonella and other bacterial contamination of their products.

3. National Residue Program

NAS RECOMMENDATION

Encourage public participation in the development and operation of the national residue program and make substantial efforts to improve public understanding.

PROBLEMS ADDRESSED

- o Public opinion polls indicate a high level of concern about residues in food.
- o Health problems associated with chemical hazards in foods must be managed by the public rather than by the individual consumer. It is often difficult to find the source of the contamination.

FSIS RECOMMENDATION

While full public understanding of FSIS' residue control efforts is laudable, the Agency felt that food safety education was considerably more important and merited the full focus of the Agency's limited funds for public education programs. The Agency noted, however, that ILA had considered the need for education on this issue during its recently completed Issues Management exercise. As a result, ILA will prepare a consumer-oriented fact sheet on the residue program, explaining in nontechnical terms how the Agency works to prevent harmful residues from entering the food supply. This fact sheet will be available to anyone requesting information on the subject as well as for special public education programs. Furthermore, FSIS should make more widely available documents such as "Compound Evaluation and Analytical Capability Annual Residue Plan," which explains the philosophy and scope of the National Residue Program. This issue was also discussed in the Residue Control Chapter (III) with recommendations cited to improve public participation.

PUBLIC EDUCATION PROBLEM AREAS

Problems identified by NAS	Additional problems identified by Committee	Relevant NAS Recommendation
<p>1. Meat and poultry were implicated in over half of the food-borne disease outbreaks reported to the CDC from 1968-1977.</p>		<p>--Educate the general public, health care personnel, educators and Extension Service workers on the safe handling of meat and poultry</p>
<p>2. Enteric pathogens are a major health problem and an economic burden.</p>	<p>Insufficient baseline data exists to know the full extent of the food poisoning problem.</p>	<p>--Procedures on safe handling and processing of meat and poultry in the kitchen are well established and should be reemphasized to the public through appropriate education vehicles.</p>
<p>3. At high risk from food-borne microbial infections are young children and the elderly.</p>	<p>Healthy adults may also suffer. Government education efforts are not generally directed to specific audiences and needs.</p>	<p>--Expand the information program and continue preparing packets of information (e.g., literature, films, and slides) for teachers and educational institutions, health care providers, extension services and the general public.</p>
<p>4. The major contributing factors to outbreaks of food-borne illness in food-service establishments and homes are leaving cooked foods at room temperature, refrigerating cooked foods in large containers, preparing food a day or more before serving it, and cross-contamination of equipment and utensils.</p>	<p>Food safety messages are complex to communicate to consumers and food handlers. Insufficient data exists on the knowledge of and attitudes towards safe food handling practices by consumers, doctors and other health care providers, institutional food workers and the news media.</p>	
	<p>5. Federal, state and local government education efforts are piecemeal and largely uncoordinated.</p>	<p>--Encourage individual consumer responsibility for food safety through effective education programs aimed at the general public beginning with the school-aged population.</p>

ATTACHMENT A - Continued

Problems identified by NAS	Additional problems identified by Committee	Relevant NAS Recommendation
	<p>6. Industry is reluctant to do food safety consumer education.</p>	<p>--From a disease control standpoint, labels, stickers or inserted leaflets should be used to provide useful information, when appropriate, on safe ways to thaw, cook and handle (e.g., cool and reheat) cooked products and list precautions to avoid cross-contamination.</p>
<p>7. Health problems associated with chemical hazards in foods must be managed by the public rather than by the individual consumer. It is often difficult to find the source of the contamination.</p>	<p>Public opinion polls indicate a high level of concern among the public about residues in food.</p>	<p>--Encourage public participation in the development and operation of the national residue program and make substantial efforts to improve public understanding.</p>

ATTACHMENT B - PUBLIC EDUCATION

ANALYSIS OF POTENTIAL TARGET GROUPS FOR FOOD SAFETY EDUCATION PROGRAM

Who's at Risk	Target Audiences/ Communications Links	Why Needed
Infants/pre-schoolers	parents home day care providers institutional day care and pre-school care providers	prevention/ high risk/ high inci- dence
Elementry school kids	self parents teachers after-school care providers school food service workers contract food services	education habits be- ing formed
Junior high/high school kids	self parents teachers school food service workers contract food services fast food restaurants	do cooking in the home/ work in fast food restau- rant/learn- ing habits
Young adults/new cooks	self	first cook- ing experi- ence
Elderly	self children nursing homes meals-on-wheels government organizations health care providers senior citizen organizations	high risk/ high inci- dence
Immigrants Non-English speaking persons Handicapped persons Low literacy/illiter- ate	self organizations and institu- tions which deal with the groups community organizations	new culture/ high risk/ little or no benefit from current pro- gram
Low income	self USDA programs Community organizations EFNEP public health care providers	little bene- fits from current pro- gram

ATTACHMENT C
MEMBERSHIP OF PUBLIC EDUCATION COMMITTEE

COMMITTEE CHAIR

Karen Stuck, Chief
Information Branch
Information and Legislative Affairs
Food Safety and Inspection Service

SECRETARIAT

Irv Dubinsky, Director
Policy Analysis Office
Policy and Planning Staff
Food Safety and Inspection Service

Violet Crosby, Food Technologist
Labeling Branch
Standards and Labeling Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

Carl Custer, Staff Officer
Processed Products Inspection
Procedures Branch
Processed Products Inspection Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

Patricia Drayne, Deputy Director
Information and Legislative Affairs
Food Safety and Inspection Service

Sally Katt, Public Affairs Specialist
Special Programs
Office of Governmental and Public Affairs

Eileen Kugler, Assistant to the Administrator
Information and Legislative Affairs
Food Safety and Inspection Service

Liz Lapping, Public Affairs Specialist
Public Awareness Branch
Information and Legislative Affairs
Food Safety and Inspection Service

ATTACHMENT C CONTINUED

Gloria Logan, Public Affairs Specialist
Division of Consumer Studies
Center for Food Safety and Applied
Nutrition
Food and Drug Administration

Masoud A. Malik, Epidemiologist
Epidemiology Branch
Pathology and Epidemiology Division
Food Safety and Inspection Service

Cynthia Mercado, Director
Office of the Administrator
Equal Employment Opportunity Staff
Food Safety and Inspection Service

Robert Miller, Branch Chief
Epidemiology Branch
Pathology and Epidemiology Division
Science
Food Safety and Inspection Service

Georgia Neruda, Consumer Industry
Affairs Specialist
Public Awareness Branch
Information and Legislative Affairs
Food Safety and Inspection Service

Mary Ann Parmley, Public Information
Specialist
Printed Media Unit
Information Branch
Information and Legislative Affairs
Food Safety and Inspection Service

Jim Rasekh, Food Technologist
Standards and Labeling Division
Meat and Poultry Inspection
Technical Services
Food Safety and Inspection Service

Nancy Robinson, Director
Information Legislative Affairs
Food Safety and Inspection Service

ATTACHMENT C CONTINUED

Danielle Schor, Head
Printed Media Unit
Information Branch
Information Legislative Affairs
Food Safety and Inspection Service

CHAPTER X

RISK-BASED INSPECTION RECOMMENDATIONS

RISK-BASED INSPECTION RECOMMENDATIONS

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RISK-BASED INSPECTION RECOMMENDATIONS

A. STATEMENT OF PROBLEM

The desire to reduce government expenditures has, since the late 1970's, left the U.S. Department of Agriculture with relatively stable resources to protect the Nation's growing and more sophisticated meat and poultry supply. More recently, these resources have begun to decline as severe budgetary restrictions have been put in place. This means that priorities must be established and inspection resources allocated to the highest-risk problems.

RISK-BASED INSPECTION RECOMMENDATIONS

B. NAS RECOMMENDATIONS

The NAS report evaluated the meat and poultry inspection program on the basis of its effectiveness in protecting the public health. It found that some important hazards such as microbiological and chemical contamination were not being adequately controlled by the current inspection process. Since to be realistic it had to assume that it was unlikely that the Agency will receive significant new monies to improve its program, NAS suggested that a risk-based inspection allocation would permit the Agency to use resources shifted from non-public health-oriented activities to improve its public health protection efforts.

Some aspects of the inspection system are poorly defined in terms of objectives relevant to public health. A risk-based allocation of resources...would be valuable.

NAS also suggested that inspection activities, to be most efficient and effective, be designed around the identification and control of critical points in the process being inspected. Within plants,

(C)ritical control points should be confirmed by FSIS and monitored, as applicable, by plant personnel and verified by trained FSIS inspectors.

In the production system as a whole,

(M)eans should be found for FSIS to coordinate the control and monitoring of hazardous agents during production, where those agents enter the food supply.

To identify and quantify risks for purposes of establishing priorities, designing inspection procedures and establishing enforcement limits, NAS concluded that:

(R)isk assessment should be systematically embodied in the planning and evaluation of all phases of meat and poultry inspection.

RISK-BASED INSPECTION RECOMMENDATIONS

C. FSIS OBJECTIVES AND STRATEGIES IN THE PROBLEM AREA

FSIS agrees with the NAS report that more risk-based activities in the inspection program would improve the efficiency and effectiveness of the entire program. One of the six major organizational objectives which are expressed in the Agency's Strategic Plan states the Agency's position with respect to risk-based allocation of resources: "The allocation of inspection resources should be based on the risks to the public inherent in a product, a process, or a producer." FSIS currently uses risk-based allocations to distribute resources across all federally-inspected plants as well as within those plants. Program efficiency and effectiveness are increased as resources are shifted from lower- to higher-risk activities and targeted to detect and eliminate problems at critical locations in the animal and food production process.

However, FSIS faces two major statutory constraints in implementing risk-based inspection activities as envisioned by NAS. First, FSIS' enabling statutes require inspection of every animal slaughtered, and daily visitation of every federally-inspected plant -- establishing a minimum resource level for every plant, which the Agency cannot change without new legislative authority. Second, in addition to its public health responsibilities, FSIS statutes also require the Agency to protect against economic adulteration and mislabeling of the products it inspects. In spite of these constraints, the Agency intends to continue to move toward a risk-based inspection system.

This paper describes current and future FSIS activities designed to implement the risk-based concept of inspection. Each of the next five sections describes current and future risk-based activities in the five areas of FSIS responsibility -- slaughter inspection, processing inspection, residue control, enforcement and compliance, international inspection, and future risk-based activities.

1. SLAUGHTER INSPECTION

A risk-based allocation used in slaughter inspection procedures is the application of a quality control system for manufacturing defects. Quality control programs allow FSIS to save resources by having inspectors concentrate on the risks posed by animal diseases and other unwholesome conditions that may require condemnation of the carcass, while making plant personnel responsible for identifying and removing manufacturing defects. Starting in 1984, FSIS designed new inspection systems that combine inspection procedures with plant-operated quality control programs for both livestock and poultry.

RISK-BASED INSPECTION RECOMMENDATIONS

The purpose of instituting quality control procedures is to reduce the time required for inspection by freeing inspectors from the task of looking for manufacturing defects. Under this system, once a carcass passes the inspector, plant personnel are responsible for assuring that carcasses are free of manufacturing defects. While plant personnel have always trimmed carcasses, previously the inspector spent considerable time identifying defects, directing plant employees to trim them, and then verifying that the trimming was properly performed. Now plant personnel do all of this. FSIS then monitors the quality control program to assure that the plant has made the appropriate checks and has taken the appropriate action.

FSIS is currently testing a new poultry inspection system whereby plant personnel would be responsible for performing bird-by-bird inspection for the purpose of making whole carcass disposition. FSIS would oversee and monitor the operation -- through the use of a computerized system which would incorporate a number of control and feedback systems such as: evaluating the flock before slaughter; sampling and intensively examining a representative number of birds from the flock; and closely monitoring the plant's inspection and production processes using random sampling and continuous computerized updates of the types and amount of defects being removed from the carcasses. This kind of inspection system has been made possible because of the industry's ability to raise healthy birds and process them under a high degree of automation and quality control. FSIS is exploring the possibility of using the system to vary inspection procedures according to disease rates, for example, the elimination of inspection procedures for a particular disease in geographical areas where that disease rarely or never occurs. The system may also reveal the need for intensified inspection procedures in some situations.

The Livestock and Poultry Disease Reporting System which documents and reports the various diseases and conditions in livestock at slaughter should enable the Agency to plot the geographic distribution, incidence and prevalence of various diseases. Using this information, FSIS will be able to adjust the intensity of inspection based on risk. At this point, the Agency is just beginning to explore the potential of this database.

FSIS has contracted with NAS for a public health-risk assessment of postmortem poultry inspection to help it establish a risk-based system of poultry slaughter inspection. It has been hypothesized that few, if any, of the diseases or conditions which are now the focus of poultry slaughter inspection are public health hazards and that compliance can be effectively achieved in a predominantly quality control system. The NAS poultry study has two objectives: to analyze the public health

RISK-BASED INSPECTION RECOMMENDATIONS

risks detectable at the time of slaughter and their significance for the inspection process; and to develop methods for comparing the effects on public health of different inspection goals and strategies -- especially strategies based on sampling of carcasses.

2. PROCESSING INSPECTION

In processing inspection, the risk-based concept of inspection is mostly applied through the use of two types of quality control programs: Total Quality Control (TQC) and partial quality control. More specifically, these programs employ a HACCP-type (Hazard Analysis Critical Control Point) concept of risk-based inspection for both public health and economic objectives.

Under TQC, plant management develops a plan which establishes control points at each critical phase of product handling and processing. Data generated at these control points during production are later verified by an FSIS inspector. The plan must specify such things as the proportion of ingredients used, mixing and blending procedures, curing, smoking, cooking times and temperatures, and the methods of verifying compliance, recording each procedure, the way in which deficiencies can be identified, and the steps that will be taken to prevent unacceptable products from reaching consumers. Designated quality control personnel must have authority to stop production, hold shipments, and take appropriate action to prevent unwholesome, adulterated, or misbranded products from being produced or leaving the plant. The inspector focuses on the operation of the quality control system itself, verifying that it is producing accurate data on its critical control points and that the plant is using these data to assure compliance. Under partial quality control programs, similar procedures are established for a particular procedure or product.

Finally, FSIS has asked Congress for authority that allows the Secretary of Agriculture greater discretion to determine the frequency and intensity of inspection for all processed meat and poultry products based on the risk of noncompliance inherent in the product, process or producer. Risk will be judged on at least three criteria that will be spelled out in regulations: (1) nature and frequency of the company's processing operations, (2) adequacy and reliability of its product monitoring systems, and (3) history of compliance with inspection requirements. This would eliminate the present requirement for continuous inspection in every plant.

RISK-BASED INSPECTION RECOMMENDATIONS

3. RESIDUE CONTROL

In the area of residue control, FSIS has implemented the risk-based inspection concept in a different way. Instead of applying the principles of risk-based inspection to those areas under FSIS jurisdiction, FSIS has determined that the critical point for controlling residues is further back in the animal production chain. As a result, in 1981, FSIS and USDA's Extension Service began to teach producers the proper use of animal drugs and to build residue prevention into all stages of livestock and poultry production.

Another application of this type of risk-based inspection is the Agency's program to stem the incidence of high levels of drug residues in "bob" veal calves (calves up to 3 weeks old or weighing less than 150 pounds) through a voluntary certification program. FSIS inspectors test calves certified to be free of illegal drug residues less intensively than uncertified calves.

A third example is the cooperative residue agreement between FSIS and individual companies for early testing at a critical point where risk can be reduced. Under such agreements, when company-conducted testing suggests that a residue problem may be present, the company informs FSIS before the birds are slaughtered. Then, FSIS works with the company to uncover the source of the problem before the products enter consumer channels.

FSIS is also working with producers to reduce the number of sulfa violations in hogs. These violations had been occurring over the past years in about six percent of the hogs slaughtered under Federal inspection. Starting in 1985, FSIS, the Extension Service, and the Food and Drug Administration have made an effort to alert pork producers of the need for corrective action. The first step was a letter sent directly to 110,000 producers, informing them that the government would be stepping up enforcement to stop violators. Then, FSIS published a notice that it was considering a new regulatory program that would include in-plant testing of hogs for sulfa residue. Because testing could delay slaughter operations and have a significant impact on the industry, the Agency expects the industry to "convince" producers to maintain appropriate withdrawal periods for hogs treated with sulfa drugs.

To continue this type of risk-based inspection, FSIS has transferred more than three million dollars to the Extension Service for research projects to study livestock production systems in order to determine the critical points where contamination can occur and to develop farm management practices to avoid residue problems.

RISK-BASED INSPECTION RECOMMENDATIONS

The Agency conducts risk assessment to determine which drugs and chemicals should be monitored in domestic and imported products. The Agency has recently let a three-year contract with the Research Triangle Institute (RTI) to help develop a new system for ranking chemicals and drugs according to their toxicity and potential for leaving residues in meat and poultry. Information developed by RTI will be used to provide a "rational" basis for changes in compound emphasis in the Residue Program and will be used to facilitate the development and/or adoption of new analytical techniques for compounds for which no suitable methods exist.

4. ENFORCEMENT AND COMPLIANCE

The Planned Compliance Program is an example of risk-based inspection because compliance resources are assigned based on the risk posed by businesses. The Compliance Division of FSIS enforces regulatory requirements by following up serious violations inside Federally-inspected plants as well as by monitoring allied firms which transport, store and distribute products to consumers, such as animal food handlers, wholesalers and renderers. The risks posed by these allied firms are defined as their history of violations and/or the presence of potentially hazardous products or processes (e.g., handling meat from animals that died by means other than slaughter). The Planned Compliance Program currently covers over 50,000 firms and individuals. The frequency of review is based on the potential hazards.

Another risk-based program is the Intensified Regulatory Enforcement (IRE) program. Established in 1983, IRE recognizes that standard inspection activities may not be sufficient to enforce requirements in some plants. The objective of IRE is to establish an environment in which plant management achieves and maintains consistently acceptable operating practices. Once a plant is identified as an IRE candidate, a specific inspection plan targeting resources is drawn up based on the plant's particular problems. The plan identifies problems and related actions that each level of FSIS management should take in dealing with those problems. These problems indicate that IRE plants pose greater risks to the public and therefore require additional inspection resources.

5. INTERNATIONAL INSPECTION

Since 1979, FSIS has used an inspection process designed around the risk-based concept to improve the inspection of imported product. The process involves a computerized system called the Automated Import Information System (AIIS) and compliance-based statistical sampling to determine the intensity of inspection

RISK-BASED INSPECTION RECOMMENDATIONS

conducted on each lot of product. When a shipment arrives at a port, information on the shipment is entered into the system. Then, based on a plant's history of compliance with inspection requirements, the nature of the product, and the size of the shipment, the AIIS generates an inspection plan. This plan specifies the inspection procedures which are tailored for each shipment based upon the relative risk the shipment presents.

FSIS RECOMMENDATIONS

Future activities must build on information, e.g., from the findings of the NAS study on the entire inspection system, the NAS study on poultry slaughter inspection, and the RTI study on residue control. To make significant changes in staff assignments, the Agency needs the authority it has requested from Congress for risk-based inspection in processing plants.

ATTACHMENT A
MEMBERSHIP OF RISK-BASED INSPECTION COMMITTEE

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FOOD SAFETY AND INSPECTION SERVICE: AGENDA FOR THE FUTURE

METHODS DEVELOPMENT AGENDA RECOMMENDATIONS

RESIDUE CONTROL RECOMMENDATIONS

MICROBIOLOGICAL CONTROL RECOMMENDATIONS

DISEASE CONTROL RECOMMENDATIONS

ANIMAL ID AND TRACEBACK RECOMMENDATIONS

DATA SYSTEMS RECOMMENDATIONS

TECHNICAL CAPABILITY RECOMMENDATIONS

PUBLIC EDUCATION RECOMMENDATIONS

RISK-BASED INSPECTION RECOMMENDATIONS